

About the Editors

Hugh B. Wellons (Editor-in-Chief and chapter author) is a member of Spilman Thomas & Battle, PLLC, a mid-Atlantic, full-service business law firm. Hugh also was executive editor and author of the first edition of *Biotechnology and the Law*. He has represented clients in life sciences development for about 20 years. He typically works as “outside general counsel” for startup and early-stage life sciences companies. As an example, he recently helped a preclinical-stage client obtain a \$10 million investment commitment from a large Northeast venture capital company. Hugh lectures frequently on business law, funding, and intellectual property licensing related to life sciences and other technology companies. Hugh also is former chair of the American Bar Association (ABA) Biotechnology Law Committee, former chair of the ABA Section of Science & Technology, former board member of the ABA Bioethics Committee, and current liaison to the ABA Commission on Disability Rights. Hugh also is former board member of the local mental health association Opera Roanoke, and current board member of Central Virginia Legal Aid. He also is past president of the Roanoke Bar Association and the Roanoke Law Foundation.

Robert F. Cople (Editor-in-Chief and chapter author), Cople & Associates PC, is an arbitrator, mediator, investigator, and litigation strategy consultant. Bob also was an editor and author of the first edition of *Biotechnology and the Law*. He helps to solve disputes involving technology and science issues, including intellectual property, biotechnology, information technology, cybersecurity, telecommunications, high-tech manufacturing, the environment, and health care. He was on the ground floor applying alternative dispute resolution (ADR) to the rapidly growing cannabis industry. Bob frequently lectures on law and technology issues both in law schools and professional organizations. He has authored more than 40 books and articles. Bob is recognized as an organization leader, both statewide and nationally, serving as the chair of the board for the Arizona State University

Center for Law, Science, and Innovation, chair of the ADR Section of the Arizona State Bar Association, and member of the Intellectual Property Section Executive Council, among other positions. Bob worked as a litigator of complex issues and a regulatory expert for large law firms in Denver and Phoenix and was Senior Litigation Counsel for Motorola. In addition, he was a judicial law clerk for a federal district judge and for a state supreme court chief justice. He received his B.A., M.A., and J.D. from the University of Nebraska, and his Ph.D. from the University of North Carolina at Chapel Hill. Bob was the executive editor of the *Nebraska Law Review* and is a Certified Information Privacy Professional (CIPP/US).

About the Authors

Afia Asamoah (chapter author) currently serves as Senior Counsel and Trust and Compliance Officer at Verily Life Sciences, formerly Google Life Sciences, an Alphabet company. She leads the product counsel, compliance, policy, and regulatory affairs teams, reporting to the general counsel with a dotted line to the chief executive officer. Afia was recruited as the first lawyer to join Google[x] life sciences team, Google's business unit dedicated to developing moonshot solutions to solve global problems. Prior to joining Google, Afia counseled pharmaceutical, biotechnology, and medical device clients on a range of health care, regulatory, and compliance issues at Covington & Burling LLP. From 2009 to 2011, Afia advised senior leaders and staff as a special assistant in the Office of the Commissioner at the Food and Drug Administration (FDA). She received four awards while at the agency, including the FDA Commissioner's Special Citation. Afia received her undergraduate degree from Harvard University, M.P.P. from the John F. Kennedy School of Government, and J.D. from Harvard Law School.

Michelle G. Breit (chapter author) is the founder and principal of Breit Law, PC, a Scottsdale, Arizona, law firm that focuses on intellectual property and business litigation. Michelle is a highly experienced intellectual property and commercial litigator, who launched her practice in Silicon Valley, representing technology companies. She represents clients in complex patent, copyright, and trademark infringement actions, trade secret misappropriation disputes, and all other aspects of intellectual property protection. In addition to her intellectual property litigation practice, Michelle has extensive experience representing and advising clients in business disputes and corporate matters, including breach of contracts, partnership and corporate disputes, dissolutions, unfair competition, and employment termination, among others. Before beginning her private practice, Michelle served as judicial law clerk and a staff attorney for the Supreme Court for the State of California, Central Staff. She received her B.A. from the University of

California, San Diego, and J.D. from the University of California Berkeley School of Law, Boalt Hall.

Eileen Smith Ewing (editor and chapter author). If *Webster's Dictionary* had a picture for “biotech lawyer,” it might be Eileen’s. In her career, she has represented many startup biotech companies, as well as multinational, Big Pharma companies. Although her specialty is international joint venture, particularly in the Pacific Rim, she has also formed companies, negotiated university licenses, provided legal strategic advice, and, well, about everything else a business lawyer might do. A Harvard University graduate summa cum laude with a Columbia School of Law diploma, as well as an M.A. and an M.Phil. from Columbia in Japanese, she now practices in Boston, Massachusetts. Eileen has seen most business aspects of biotech law many times. She is a multiple chapter author and former co-editor-in-chief of the first edition of this book, as well as former chair of the American Bar Association’s Section of Science and Technology and its Biotechnology Committee. She currently is co-chair of the section’s Medical Devices Committee and acts as liaison to past chairs. Eileen has published more than 50 articles on corporate and intellectual property law related to life sciences, and she serves as co-chair of the National Council of Lawyers and Scientists. Eileen continues to give back to the profession in many ways.

Andrew T. Hoyne (chapter author) is a senior partner with Polsinelli PC, a national law firm with offices in 20 major cities throughout the United States. He practices business and corporate law focused upon the representation of life sciences and other technology-based companies, venture capital funds, other investors, and research entities. Among other awards and recognitions, Andy is listed in *The Best Lawyers in America* as the Venture Capital Lawyer of the Year for St. Louis (2018 and 2014–2015), the Biotechnology Lawyer of the Year for St. Louis (2017), and for Technology Law; by Chambers USA for Business, Corporate/Mergers and Acquisitions; and as a “Life Sciences Star” for transactional work in *LMG Life Sciences*. He is a former Vice Chair of the American Bar Association Biotechnology Committee and was a chapter co-author of the first edition of *Biotechnology and the Law*.

Amy Kearbey (chapter author) advises clients on health care fraud and abuse laws, coverage and reimbursement matters, and digital health strategy. She represents a broad range of health industry stakeholders, including hospital systems, medical societies, physician practice management companies, pharmaceutical and medical device companies, clinical laboratories, and data informatics companies. Her practice includes developing compliance policies and programs, managing audits and investigations, securing Office of Inspector General Advisory Opinions, and defending False Claims Act cases. Amy also assists clients with coverage and reimbursement strategies, including payment appeals and advocacy work. Amy also has extensive experience advising on digital health strategy, with an emphasis on the complex issues presented by offerings relating to value-based payment models and innovative life sciences solutions.

Areta L. Kupchyk (chapter author) is a partner and co-chair of the Food and Drug Administration (FDA) Practice Group at Foley Hoag LLP. Areta served at the FDA as Associate Chief Counsel for Drugs and Biologics and Assistant General Counsel of Litigation for ten years between 1993 and 2003. During her tenure at FDA, Areta contributed significantly to the development of some of FDA's most dynamic issues, including the regulation of human cellular and tissue therapies, data integrity, and enforcement strategies. In her practice, Areta advises small and large biotechnology companies around the globe, domestic human tissue and eye banks, health care institutions, inventors, investors, and individuals on FDA regulatory preapproval and postapproval issues. Areta helps clients with novel biotechnology products develop strategies to facilitate lean and expedited regulatory reviews to obtain FDA approvals and clearances. Areta earned her J.D., with honors, from the University of Maryland School of Law and was inducted into the Order of the Coif. Areta is admitted to the bar in Maryland and the District of Columbia.

Michelle M. LeCointe (chapter author) is special counsel at Baker Botts LLP, a multinational full-service law firm. Michelle's practice centers on providing coordinated strategic assessments for intellectual property portfolios and implementing this advice through patent litigation, opinions, patent procurement, and licensing. Michelle's substantial involvement in

international intellectual property protection extends far beyond prosecution of worldwide patent portfolios to include proceedings before the European Patent Office opposition and appeal boards, invalidation proceedings in China, and negotiations among multinational parties. Major technical areas of focus include life sciences, pharmaceuticals, medical devices, and electrochemical devices. Michelle received her J.D. from Columbia University and B.A. from Harvard University.

Erika Lietzan (editor and chapter author) is an associate professor at the University of Missouri School of Law, where she researches, writes, and teaches primarily in the areas of food and drug law, intellectual property, and administrative law. Prior to joining academia, she spent 18 years practicing food and drug law, including eight years as a partner at Covington & Burling in Washington, D.C. She is an elected member of the American Law Institute and has been named a “Best Lawyer in America” in Food and Drug Administration law for five years in a row and in biotechnology law for 11 years in a row.

Gary E. Marchant (chapter author) serves as the Regents’ Professor and Lincoln Professor of Emerging Technologies, Law & Ethics, and Faculty Director of the Center for Law, Science & Innovation, at the Sandra Day O’Connor College of Law, Arizona State University (ASU). He also serves as a professor at the School of Life Sciences and Distinguished Sustainability Scientist at the Global Institute of Sustainability at ASU. Gary’s research interests include the governance of emerging technologies, legal aspects of personalized medicine, use of genetic information in the legal system, legal aspects of risk assessment and risk management, and the application of science and technology in the legal system. He teaches courses such as Law, Science & Technology; Artificial Intelligence & the Law; Genetics and the Law; Biotechnology: Science, Law, and Policy; Health Care Technologies; and Big Data, Privacy, and Emerging Technologies. Prior to joining the college faculty in 1999, Gary was a partner at the Washington, D.C., office of Kirkland & Ellis, where his practice focused on environmental and administrative law. During law school, he was editor-in-chief of the *Harvard Journal of Law & Technology* and editor of the *Harvard Environmental Law Review* and was awarded the Fay Diploma (awarded to top graduating

student at Harvard Law School). Gary frequently lectures about the intersection of law and science at national and international conferences. He has authored more than 120 articles and book chapters on various issues relating to emerging technologies. Among other activities, he has served on five National Research Council committees, has been the principal investigator on several major grants, and has organized dozens of academic conferences and workshops on law and science issues.

W. Ken Maready (chapter author) is Of Counsel to Hutchison's corporate practice group and has more than 17 years of experience working with founders, management, boards of directors, and investors of technology companies, primarily in connection with M&A, private equity, venture capital, and angel and startup activity. Ken graduated magna cum laude from Wake Forest University School of Law, where he focused on corporate, securities, tax, and business law while serving as Editor-in-Chief of the *Wake Forest Law Review*. After law school, he practiced corporate and transactional law in Charlotte, Washington D.C., and the Research Triangle Park before moving to the New River Valley area of Virginia. He has worked with large national law firms and boutique firms and in-house as general counsel for a venture-backed company. Ken is a member of the Mergers & Acquisitions Committee and the Private Equity & Venture Capital Committee of the Business Section of the American Bar Association and is active in the Roanoke-Blacksburg Technology Council, co-chairing its Access to Capital Committee.

Linda L. McCarty (chapter author) is a counsel at Spilman Thomas & Battle, PLLC, a mid-Atlantic, full-service business law firm. She represents health care institutions, pharmaceutical companies, site management organizations, and independent research sites on a wide range of matters relating to clinical research, including devising and implementing practical strategies to enable the integration of clinical research within a health care system; compliance with laws and regulations; and drafting and negotiation of clinical trial agreements, indemnification agreements, and regulatory documents. Prior to joining Spilman Thomas & Battle, PLLC, she was the in-house general counsel for a leading U.S. clinical research site network, with responsibilities for legal activities, regulatory affairs, corporate

compliance, and quality assurance. Linda earned her B.A. from San Diego State University, J.D. from New England School of Law, and LL.M.-Tax Law/Taxation from Boston University School of Law.

Cortney E. Mendenhall (chapter author) is a shareholder at Polsinelli PC, an Am Law 100 firm with more than 800 attorneys in 20 offices and named Law Firm of the Year in Health Care by U.S. News and World Report's "Best Law Firms" 2018. She has represented clients in the life sciences industry for more than ten years, often acting as outside general counsel. Cortney has significant experience advising clients with respect to entity selection and formation, negotiation of initial and subsequent rounds of equity financing, negotiation of licensing agreements, technology transfer agreements, material transfer agreements, clinical trial agreements and other commercial agreements, and structuring and negotiation of exit transactions. She lectures frequently on issues relevant to life sciences companies and is very involved in the Kansas City metropolitan area startup and angel investment communities.

Stephen A. Owens (chapter author) is a partner with the global law firm Squire Patton Boggs (U.S.) LLP, where his practice focuses on environmental and energy issues. Before joining Squire Patton Boggs, Steve served as Assistant Administrator of the U.S. Environmental Protection Agency (EPA) in charge of EPA's Office of Chemical Safety & Pollution Prevention. Appointed by President Obama and unanimously confirmed by the U.S. Senate, Steve was responsible for managing U.S. regulatory and scientific programs on pesticides and industrial chemicals, including biotechnology, under the Toxic Substances Control Act, the Federal Insecticide, Fungicide, and Rodenticide Act, and other statutes. Immediately prior to joining EPA, Steve served as Director of the Arizona Department of Environmental Quality in the cabinet of Governor Janet Napolitano, and, before that, he was in private practice in Phoenix, representing clients on the full range of federal and state environmental laws. Steve began his legal career in 1982 as Counsel to the Subcommittee on Investigations and Oversight of the U.S. House of Representatives Committee on Science and Technology, where he assisted with the first-ever congressional hearing on the environmental implications of genetic engineering, chaired by then-Representative Al Gore. Steve later served as Chief Counsel and State Director for Senator

Gore. Steve graduated with honors from Brown University in 1978 and received his J.D. degree in 1981 from Vanderbilt Law School, where he was editor-in-chief of the *Vanderbilt Law Review*.

Dan Pancamo (chapter author) is counsel in the New Orleans office of the regional law firm Phelps Dunbar, LLP. He practices in commercial and transactional matters, regulatory matters, and construction (with an emphasis on medical construction). He is a 1989 graduate of Tulane Law School. He is formerly a member of the board of directors of the National Tay-Sachs & Allied Diseases Association, one of the nation's oldest genetic disease support organizations.

Jennifer Korpacz Pelaia (appendix author) is the Director of Library Services at Covington & Burling LLP, where she previously served as Food and Drug Librarian, and Assistant Librarian managing Research Services, while specializing in food and drug, and legislative research. A graduate of the University of Colorado at Boulder, she earned her law degree from St. John's University, and is admitted to practice in New York. She obtained her master's in library science from the Catholic University of America.

Paul Radensky (chapter author) is a Medicare law and policy authority who is board-certified in internal medicine and who helps clients navigate federal legislative and regulatory processes related to Medicare coverage, coding, reimbursement, and compliance as well as regulatory and promotional compliance matters with the Food and Drug Administration (FDA). Paul represents some of the country's most innovative developers of pharmaceuticals, biologics, medical devices, and diagnostics before Congress, the U.S. Department of Health and Human Services, the Centers for Medicare and Medicaid, FDA, and other federal agencies.

Tom Redick (chapter author) practices international environmental law and liability prevention at Global Environmental Ethics Counsel LLC in St. Louis, Missouri. His clientele includes corn and soy growers, grain traders, and grocery manufacturers, as well as high-tech clients. He was the first lawyer to serve as president of the Council for Agricultural Science & Technology, from 2010 to 2013, and served on the governing council of the American Bar Association Section on Environment, Energy, and Resources. He has handled several billion-dollar toxic tort cases including the Syngenta China corn litigation (2016–2017), the Erin Brockovich cases in 1999

(*Aguayo et al. v. PGE*), and the first trial of a “genetically modified organism” personal injury case in 1993 involving l-tryptophan (*Di Rosa v. Showa Denko KK*). He won the San Diego Volunteer Lawyer Program’s highest award, the Wiley Manuel award. He studied history, philosophy, and law at the University of Michigan in Ann Arbor.

Rebecca Frigy Romine (chapter author) is a shareholder at Polsinelli PC. She practices in the firm’s nationally recognized health law department and specializes in data privacy and security issues, including the Health Insurance Portability and Accountability Act (HIPAA), the Health Information Technology for Economic and Clinical Health (HITECH) Act, 42 C.F.R. part 2, state law, and other federal and international laws. Rebecca represents a diverse mix of clients across the health care sector, from large health systems to startup tech companies. Rebecca assists these clients with general compliance and transactional advice, as well as incident and breach response, and government audits and investigations. When Rebecca is not assisting clients, she is a busy wife and mom of two. She received her J.D. and M.P.H.-Health Policy from Saint Louis University, and B.S. from the University of Notre Dame.

Margaret J. Sampson (chapter author) is a partner at Baker Botts LLP, a multinational full-service law firm. Margaret has a global, strategic intellectual property transaction and patent counseling practice focused in the areas of life sciences, pharmaceuticals, research tools, and medical devices. Intellectual property and technology clients turn to Margaret for evaluating, structuring, negotiating, and documenting major transactions. She has extensive experience advising clients in evaluating patent portfolio positions; analyzing freedom-to-operate issues; identifying and evaluating targets for potential investment, mergers, or acquisitions; and assisting with joint development, inbound, and outbound licensing agreements. Margaret’s experience also includes Hatch-Waxman Act patent litigation, patent term extensions and adjustments, clinical and manufacturing agreements, and royalty acquisitions. Margaret’s scientific background is in molecular genetics, recombinant DNA, and stem cell research. Her J.D. is from the University of Texas Law School, Ph.D. in Molecular and Human Genetics from Baylor College of Medicine, and B.A. from the University of Texas.

Robyn S. Shapiro (chapter author) is founder and attorney at Health Sciences Law Group, LLC, in Fox Point, Wisconsin. She has worked extensively in health law matters involving clinical research, genetics, biotechnology, treatment decision making, bioethics issues, medical staff matters, health information privacy issues, informed consent, regulatory and licensing matters, and corporate and commercial issues faced by pharmaceutical and medical device manufacturers and hospitals and academic medical centers engaged in research. Robyn's past position as Ursula von Der Ruhr Professor of Bioethics at the Medical College of Wisconsin and her 26-year leadership as director of the Bioethics Center at the Medical College of Wisconsin complement her wide-ranging experience in health law. Robyn is listed in the *Best Lawyers in America* and a number of *Who's Who* publications. She was included in Nightingale's 2006 list of "Outstanding Hospital Lawyers" in the nation; she was awarded 2019 *Best Lawyers* "Lawyer of the Year" Award for Health Care Law in Milwaukee; in 2011, she was named Milwaukee's "Health Care Lawyer of the Year" by *Best Lawyers*; and in 2013, 2014, and 2015 she was ranked by Chambers USA as "Leaders in Their Field/Life Sciences: Regulatory/Compliance (Nationwide)." Robyn has written more than 50 articles and book chapters on health law topics that have been published in peer-reviewed journals and books, and she has lectured on a wide variety of health law, research compliance, and bioethics topics throughout the world. Robyn has served as an appointed member of the U.S. Department of Health and Human Services, National Institutes of Health Recombinant DNA Advisory Committee (RAC), the RAC Clinical Trials Working Group, and the RAC Bio-Safety Working Group, and she has also served as an appointed member of the Food and Drug Administration Drug Safety and Risk Management Advisory Committee and appointed member of the U.S. Department of Health and Human Services Secretary's Advisory Committee on Xeno-Transplantation. Robyn has been named an American Bar Association (ABA) fellow, she serves as co-chair of the Wisconsin ABA fellows, she has served as chair of the ABA Individual Rights and Responsibilities Section and the ABA Special Committee on Bioethics and the Law, and currently she serves as the ABA Health Law Section's delegate to the House of Delegates, and council member of the ABA Health

Law Section. From 2013 to 2016, Robyn served as an appointed member of the Law360 Life Sciences Editorial Advisory Board. She earned her J.D. from Harvard Law School and her B.A., summa cum laude with highest distinction, from the University of Michigan, where she was Phi Beta Kappa. She is admitted to the bars of Wisconsin and the U.S. Supreme Court.

Snehal Trivedi (chapter author) is an associate in the Food and Drug Administration (FDA) Practice Group at Foley Hoag LLP. Snehal focuses her practice on FDA policy and regulatory matters and advises biotechnology, pharmaceutical, device, and food companies on preapproval and postapproval requirements. Snehal draws upon ten years of pharmaceutical industry experience to conduct complex regulatory analyses; draft and negotiate license, distribution, and clinical trial agreements; and develop regulatory strategies to expedite pathways to market. She also facilitates due diligence efforts related to FDA and Drug Enforcement Administration regulations and state pharmacy laws. Snehal earned her Pharm.D. from the University of the Sciences and her J.D. from the Campbell Law School.

Jeffrey A. Van Doren (chapter author) practices law in Blacksburg, Virginia, where he focuses on immigration and employment law issues. Listed in *The Best Lawyers in America* for both immigration and employment law, he concentrates on assisting United States-based and foreign companies with their business immigration needs. He represents both public and private employers in securing nonimmigrant (temporary) and immigrant (permanent) visas on behalf of employers and employees. Jeff also has extensive experience representing clients in discrimination, wrongful discharge, wage and hour, breach of contract, and other employment claims before federal and state courts. Jeff is a former national board member of Goodwill Industries International, Rockville, Maryland, and has served numerous terms as director of the local Goodwill member organization in Roanoke, Virginia. He received his B.A. from the University of Dayton and J.D. from the University of Pennsylvania.

William N. Wofford (editor and chapter author) is a corporate transactional lawyer and drug development entrepreneur. Bill leads the biopharmaceutical and life sciences practice at Hutchison PLLC, a Raleigh, North Carolina-based boutique law firm, where his practice focuses on structuring

and negotiating transactions for drug development, biotechnology, medical device, and health care services companies, and financial, strategic, and philanthropic investors. He helps growing and established companies raise capital, acquire and out-license technology, collaborate with strategic partners, and engage in mergers and acquisitions. Bill is also an investor in and advisor to various drug development companies and a principal with Arrivo Bioventures, a Research Triangle biopharmaceutical development company. Bill earned his B.A. and J.D. from the University of Virginia. He serves on the board of directors of the Eco Institute at Pickards Mountain and supports environmental, mental health, and social justice causes.

Craig B. Young (chapter author) is a partner in the Washington, D.C., and Richmond, Virginia, offices of the national firm Kutak Rock LLP. Craig specializes in bankruptcy law and commercial litigation where he represents secured and unsecured creditors including creditors' committees; financial institutions and lenders; asset purchasers; landlords and tenants; equipment lessors and lessees; licensors and licensees of intellectual property; and companies that provide goods and services. During his career, Craig has authored numerous articles, regularly presented continuing legal education courses, and is the co-author of *Bankruptcy and Its Impact on Intellectual Property*, published by the American Bankruptcy Institute. Craig is also an adjunct professor of law at Antonin Scalia Law School at George Mason University where he has taught Bankruptcy Law for 20 years. He is active in his community, serving as a conciliator for the Fairfax County (Virginia) Circuit Court and as supervisor of the Northern Virginia Bankruptcy Assistance Clinic. Craig earned his bachelor's degree and an MSM from the American University in Washington, D.C. He received his J.D. from George Mason University School of Law where he was a published associate editor of the *George Mason Law Review*. After law school, he served as law clerk to U.S. district judges Albert V. Bryan and James C. Cacheris in the Eastern District of Virginia.