

About the Authors

Ranee Adipat is Counsel at Ropes & Gray. She represents hospitals, health systems, academic medical centers, clinically integrated networks, and other health care companies in sophisticated, precedent setting transactions. She has over a decade of corporate experience, including in mergers, acquisitions, joint ventures, and affiliations. Ranee provides clear, concise counsel to management and in-house legal teams while working seamlessly with consultants, financial advisors and co-counsel to ensure transaction completion.

Alan J. Brudner is the Chair of the Bioethical Issues Committee of the New York City Bar Association. Alan is a litigation partner at Katten Muchin Rosenman, LLP, where he works with a team of health care litigation, regulatory, and white-collar lawyers in representing hospitals, hospital associations, and other health care providers in litigation and investigations under the False Claims Act, reimbursement audits and disputes, and other health care audits, hearings, trials, and appeals. Alan is the former head of litigation and enforcement for UBS Investment Bank, and served as an Assistant United States Attorney for the Southern District of New York. He is a 1983 graduate of New York University School of Law, and a 1979 graduate of Vassar College.

Colin Callahan is a Partner at Flannery Georgalis LLC in Pittsburgh and a former federal prosecutor from the Western District of Pennsylvania, where he uniquely served in both the civil and criminal divisions. He focuses his practice on defending individuals and organizations in complex criminal, civil, and regulatory matters—with an emphasis on matters involving health care and government contracting fraud. During his time as a federal prosecutor, Colin investigated and prosecuted a wide variety of criminal and civil cases, including matters involving health care fraud, kickbacks/bribery, money laundering, and violations of the False Claims Act. Before joining the U.S. Attorney's Office, Colin was an attorney at two prominent law firms in Washington D.C. and clerked at both the trial and appellate court levels for two federal judges.

Samuel (Sammy) M. Chang is an associate attorney at Athene Law, LLP. His practice focuses on Medicare and Medicaid reimbursement issues, regulatory compliance, antitrust, and health care policy for hospitals, health systems, and health care providers. He also contributes annually to the California Medical Association's Physician Legal Handbook for Medicare, Medi-Cal, and managed care issues. Prior to joining Athene Law, Sammy was a health policy researcher whose research has been featured or utilized by the California's Office of Statewide Health Planning and Development, the California Senate Committee on Business, Professions, and Economic Development, the California Assembly Committee on Health, the California Department of Justice, and the Congressional Budget Office. Sammy has also presented at the National Academy for State Health Policy Annual Meeting, the AcademyHealth National Health Policy Conference, and the Los Angeles State of Reform Health Policy Conference regarding his health policy research.

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Danielle Pelfrey Duryea directs the Compliance Policy Clinic and the Health Justice Practicum at Boston University School of Law. Before joining BU Law, she taught at the University at Buffalo School of Law—State University of New York. There she taught health law and founded the Health Justice Law & Policy Clinic; represented the law school across the university as Assistant Dean for Interprofessional Education & Health Law Initiatives; and served as associate director of the interdisciplinary UB Center for Successful Aging. Previously, she practiced in the government enforcement practice group at Ropes & Gray LLP for five years, where she focused on pharmaceutical and medical device regulation, enforcement, and compliance. She also co-founded the firm’s nationally-recognized pro bono medical-legal partnerships.

Jeff Dutson is a Financial Restructuring partner in King & Spalding’s Atlanta office, with a focus on representing banks and other secured lenders in connection their most complex workouts, restructurings, and bankruptcy matters. Jeff also frequently represents corporate debtors in Chapter 11 bankruptcy cases throughout the country as well as buyers and sellers in distressed M&A transactions. Jeff’s practice spans a wide variety of industries, including the restaurant, health care, energy, transportation, manufacturing, and aviation industries.

Deborah Farringer is Associate Dean for Academic Affairs; Associate Professor of Law; and Director of Health Law Studies at Belmont University College of Law. She has taught a variety of courses including Health Law, Health Care Business and Finance, Contracts & Sales, Business Associations, Health Care Fraud and Abuse, Bioethics, and Mental Health Law. Her scholarship explores the operation and impact of health laws and health policy on providers and suppliers, with a special emphasis on the unique challenges facing the health care industry in the digital space. She also serves as the faculty supervisor for the Belmont Health Law Journal and is the coach of the health law transactions moot court team. Prior to joining Belmont University College of Law, Deborah served as Senior Associate General Counsel for Vanderbilt University, focusing on matters for Vanderbilt Medical Center, and at a large law firm in its health care regulatory group. Deborah graduated *summa cum laude* from the University of San Diego, and received her J.D. from Vanderbilt University Law School where she was a member of the Order of the Coif. Following law school, she clerked for Judge H. Emory Widener, Jr. on the United States Fourth Circuit Court of Appeals.

Andrea Frey is an attorney in the San Francisco office of Hooper, Lundy & Bookman. Her practice focuses on transactional and health care regulatory matters, with an emphasis on health privacy, digital health, licensure and certification, scope of practice, and medical staff issues. She regularly assists providers, including hospitals, health systems, health care districts, digital health providers, and health care businesses, on general corporate and regulatory matters, including compliance issues presented by telehealth. She also co-chairs the firm’s digital health practice.

Jeremy A. Gunn is an associate at Bass Berry & Sims in Nashville, Tennessee. He concentrates his practice on complex commercial litigation representing life science and health care companies. He has represented clients in a wide variety of matters, including consumer class actions, contract disputes, civil antitrust litigation, and product liability litigation. Before joining Bass, he clerked for the Hon. John Preston Bailey of the U.S. District Court for the Northern District of West Virginia.

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Clint Hermes leads the Clinical Research practice at Bass, Berry & Sims PLC. Clint has served as Chief Legal Officer of St. Jude Children's Research Hospital, General Counsel of a Cornell-affiliated academic medical center in the Middle East, member of numerous Institutional Review Boards, and advisor to a foreign government on biomedical research regulation and policy. He advises hospitals, universities, life sciences companies, and foundations with the contracting, operational, and regulatory aspects of clinical trials, including the Common Rule, FDA regulations, research funding, conflicts of interest, creation and sharing of data and tissue repositories, research misconduct, and the globalization of biomedical research. Clint graduated *magna cum laude* from both Yale University and Harvard Law School.

Nicole Huberfeld is the Edward R. Utley Professor of Health Law and Professor of Law at Boston University School of Law and School of Public Health. Her work studies the intersection of health law and constitutional law. She researches the law's impact on vulnerable populations through governance and policy choices made in health care, public health, and social programs, with particular interest in Medicaid and health reform. She is co-author of two casebooks and many book chapters, journal articles, and commentaries, including a five-year study of the early implementation of the Affordable Care Act (What Is Federalism in Healthcare For?, *Stanford Law Review*, 2018, with Gluck). Her work has been cited in judicial opinions by the U.S. Supreme Court and other federal and state courts. In 2019, Nicole won the Excellence in Teaching Award at BUSPH. She has been quoted by media outlets such as *New York Times*, *Bloomberg*, *NPR*, *Congressional Quarterly*, *Washington Post*, *National Law Journal*, *Mother Jones*, *Politico*, *Univision*, *Modern Healthcare*, and *Time*.

Heath Roosevelt Ingram is an Associate at Goodwin Procter LLP in the Firm's New York Life Sciences and Healthcare practice. Heath focuses his practice on health care regulatory, compliance, transactional, and government affairs matters. He has experience in federal health care program coverage and reimbursement, value-based contracting, government investigations, drug transparency laws, drug pricing, internal investigations, health care issues arising in the context of mergers and acquisitions, HIPAA, health care licensure, the Anti-kickback Statute, Stark Law, and other health care fraud and abuse matters. He works with numerous clients, including pharmaceutical and medical device manufacturers, digital health companies, durable medical equipment manufacturers, clinical laboratories and diagnostic test manufacturers, health IT companies, and health insurance companies. Heath received his J.D. from the Northwestern University School of Law and an M.A. in Medical Humanities and Bioethics from Northwestern.

Travis Jackson is a Partner at McDermott Will & Emery. He represents health care providers in complex mergers, acquisitions, and joint ventures. He has led and closed mergers, acquisitions, and joint ventures for health systems, academic medical centers, private equity-backed organizations, and other investors, creating cutting-edge deal structures that allow clients to ensure continuity of care in their communities while diversifying the health care services they provide. He serves as a member of the American Health Law Association (AHLA) tax conference planning committee and as a member of the editorial board of Wolters Kluwer's Health Care Compliance Program Manual. Travis has been recognized in Chambers (USA) for 2021 and as one of the Best Lawyers in America for seven consecutive years.

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Cathryn (Cat) Johns is an associate in the Kansas City office of Shook, Hardy & Bacon. She focuses her practice in business litigation, where she handles matters at all stages from client counseling to pretrial to preparation for appeal. Before joining Shook in the fall of 2019, Cat was a judicial law clerk for the Hon. Bobby E. Shepherd, Circuit Judge of the U.S. Court of Appeals for the Eighth Circuit.

Karen Mandelbaum is a Senior Counsel in the Health Care and Life Sciences practice, in Epstein Becker & Green's Washington, DC and Baltimore offices. Karen advises clients on health care regulatory compliance matter and federal and state privacy and data protection laws, with a focus on the privacy implications and the development of privacy policies for websites and mobile applications. Karen also provides counsel to a variety of health care industry clients, including health care providers, health plans, insurance brokers and health IT developers on issues including data protection, software licensing, IT transactions, and information blocking matters. Before joining Epstein Becker & Green, P.C., Karen served as the Senior Advisor for Security & Privacy Policy and Governance to the Chief Information Officer at the Centers for Medicare & Medicaid Services.

Torrey McClary is a Partner at Ropes & Gray. She has tremendous depth of experience in managing acquisitions, joint ventures, and restructurings in the health care sector. She has structured and negotiated some of the most prominent and complex health system transactions in the United States in recent years, and is currently advising health systems throughout the country on a number of innovative, transformational health care transactions. She represents academic medical centers, nonprofit and for-profit hospitals and health systems, biotech companies, technology companies, and REITs in a broad range of complex corporate and transactional matters involving health care assets and operations. Torrey is expert in a variety of transaction models, including asset purchases, membership substitutions, joint operating agreements, integration and affiliation arrangements, and long-term leases.

Elaine Naughton is an associate in the Health Care and FDA practice group at K&L Gates LLP, where she assists academic medical centers, medical device companies, and pharmaceutical companies with regulatory and contracting matters related to clinical trials and human subjects research. Elaine also provides health care regulatory counsel on compliance, operational, and transactional matters, and works on such matters with a wide range of clients in the health care industry, including hospitals, health systems, academic medical centers, hospices, home health providers, urgent care centers, ambulance providers, laboratories, and specialty pharmacies. Her compliance and operational experience includes fraud and abuse inquiries, contracting, complex licensure analyses, Medicare/Medicaid enrollment and reimbursement issues, and other matters relating to the day-to-day operations of health care providers and suppliers. Elaine provides regulatory counsel to health care providers, suppliers, and private equity firms on transactional matters as well, including conducting due diligence analyses and advising on transactional documents and structuring issues, such as corporate practice of medicine restrictions, licensure and enrollment requirements, and Stark Law and Anti-Kickback concerns.

LaRae' Neal is an associate in the Philadelphia, PA office of Shook, Hardy & Bacon. She practices in the general liability litigation, product liability litigation, and business litigation groups. She assists clients in a variety of industries, including hospitality, automotive,

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Delphine O'Rourke has tackled some of the most difficult problems in health care from the C-suite and board rooms of health companies. She is a partner in the firm's Life Sciences group, a member of the Corporate Social Responsibility (CSR), Environmental, Social and Governance (ESG), and Social Impact Investing groups, a health law subject matter expert, and provides strategic guidance, technical expertise, and regulatory counsel to clients. Delphine develops and executes regulatory solutions on behalf of entrepreneurs, growth companies, health care systems, public companies, and investors, and works directly with leadership to leverage her clients' innovative solutions. She focuses her health care regulatory practice on compliance with federal laws and regulations governing access, delivery, and payment for medical care in the United States including compliance with the Anti-Kickback Statute, Stark Law, OIG civil monetary penalties law, state fraud and abuse provisions, change of ownership, corporate practice of medicine, Medicare and Medicaid reimbursement, and laws relating to non-profit health systems. Additionally, Delphine is a fierce advocate for founders in women's health and partners with them along their journey by providing critical strategic and legal advice. In addition to being a trusted and invaluable advisor for companies transforming the health and wellness industry, Delphine is an experienced health system leader and in-house counsel. Delphine was Associate General Counsel of Ascension, one of the largest private health care systems in the U.S., and now bridges the traditional health system for her clients' products, services, and investments. Delphine serves on the boards of the Columbia Law School Alumni Association, The Forum of Executive Women, and The Foundation of The Forum of Executive Women. She is Vice-Chair of the Women's Leadership Council of the American Health Law Association, member of CHIEF (a private network focused on connecting and supporting women leaders), health care expert for Endeavor (the world's leading community of high-impact entrepreneurs), and Fellows Mentor for Summit Impact (a community-powered approach to scaling global impact).

Jorge L. Rivera-Agosto, MS, HEC-C is a health care attorney and current Clinical Ethics Fellow at Northwell Health. Before joining Northwell, he was a litigator in private practice. Jorge held positions in insurance companies and government. He has a Master of Science in Bioethics from Columbia University and is a Healthcare Ethics Consultant, certified by the American Society for Bioethics and Humanities. He is also a faculty member of the Interdisciplinary Aging, Public Health, and Palliative Care Certificate Program offered at the Finger Lakes Geriatric Education Center at the University of Rochester, and a guest lecturer at several universities for topics in law and clinical ethics. Jorge is actively involved in the State and City Bars of New York and has worked extensively with underserved communities in matters related to health care and immigration.

Christopher C. Sabis heads Sherrard Roe Voigt & Harbison's Government Compliance & Investigations group and is a member of the firm's Litigation and Healthcare practices. He has extensive experience in False Claims Act (FCA) matters, white-collar fraud investigations, and general commercial litigation. Chris has significant experience in the mediation

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Angelique Salib provides health care regulatory counsel as it relates to compliance, operational and transactional matters through applicable components of the Stark Law, Anti-Kickback Statute, CMS guidance on reimbursement, and other relevant guidance. In addition, she works with hospital and health system clients on contractual arrangements, clinical research, and a broad range of compliance matters.

Elizabeth (Beth) Scarola is an Associate in the Health Care and Life Sciences practice of Epstein Becker & Green, P.C. Beth brings an insider's perspective to her health care practice. In addition to her extensive work on strategic and operational projects for a large, statewide clinically integrated network, she has hands-on scientific research experience, having conducted research in pediatric endocrinology. As a BRCA+ "previvor" and health law enthusiast, she is passionate about navigating the complexity of health care regulation and policy to promote the promise of precision medicine.

Alaap Shah is a Member of Epstein Becker & Green. Alaap serves as co-chair of the privacy, cybersecurity, and data asset management team. His practice focuses on proactive and reactive counseling and defense of health care, life sciences, and technology companies on a variety of legal and regulatory compliance issues. The breadth of Alaap's practice includes supporting clients related to health information technology, interoperability, big data analytics, digital health, artificial intelligence, establishing and testing privacy and cybersecurity compliance programs, responding to data breaches and ultimately building trust networks through contracting, compliant business models and technology architecture, and risk management and allocation strategies.

Jeremy Sherer is an attorney in the Boston office of Hooper, Lundy & Bookman where he co-chairs the firm's digital health practice. Jeremy's national digital health practice focuses on representing digital health companies from pre-seed start-ups through publicly traded platforms, as well as innovative health care providers and health systems, primarily advising on business and regulatory issues involving digital health technology. Jeremy regularly speaks on the regulation of digital health at conferences across the country, has contributed to digital health treatises published by the American Bar Association and the American Health Law Association as well as the Massachusetts Health and Hospital Law Manual, and is a member of the legal faculty at the Center for Telehealth and e-Health Law.

Thomas J. Sullivan is a Partner in Shook Hardy & Bacon's Philadelphia office with significant experience advocating for clients in the defense of high-profile, complex business disputes and tort litigation of all types, including class actions and other aggregate litiga-

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