EPSTEIN BECKER GREEN

Andrew (Andy) P. Rusczek

he / him / his

Member of the Firm

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Attorney Andy Rusczek provides regulatory and compliance advice to a broad range of clients in the health care and life sciences industries, including hospitals, academic medical centers, and related providers as well as pharmaceutical, medical device, and biotechnology companies. His practice encompasses many legal areas within the health care and life sciences space.

Andy has particular experience with respect to the following types of matters, among others:

- Hospital and health plan transactions and affiliations, including negotiations of definitive agreements, revisions to governance documents, regulatory approvals, and diligence matters
- Regulatory and compliance issues for pharmaceutical and device companies
- Formation and operation of accountable care organizations, physician-hospital organizations, independent practice associations, and related multi-provider networks
- Compliance with the federal anti-kickback statute, the Stark law, and other fraud and abuse laws, such as in the context of product discount arrangements, relationships with physicians, and health care transactions
- Development of comprehensive privacy and security policies and related guidance documents in accordance with the European Union General Data Protection Regulation (GDPR) and HIPAA, HITECH, and state privacy laws
- Human subjects research and related issues, both domestically and internationally

Additionally, Andy has gained a strong understanding of the operational aspects and business of pharmaceutical and device companies through prior on-site placements at three different companies. In these positions, he advised clients on various legal issues, including fraud and

abuse laws, clinical trials and related issues (such as privacy, subject recruitment, site contracting, informed consent forms, and FDA requirements for INDs), market research, promotional review activities, patient assistance programs, group purchasing organization and customer contracts, discount and pricing arrangements, sales representative contracts, and state manufacturer conduct and disclosure laws as well as FDA regulations and other legal requirements related to operating a start-up or commercial company.

Before joining Epstein Becker Green, Andy was a partner at a Boston law firm and served as chair of its Health Care & Life Sciences Group. He also served as a community member of the Brigham and Women's Hospital Institutional Review Board (2010-2015).

While attending the University of Pennsylvania Law School, Andy earned a Master of Bioethics from the University of Pennsylvania School of Medicine to better assist future clients with ethical issues involved with human subjects research.

Experience

Guided Manufacturer Through Acquisition

Assisted Manufacturer with State Board of Pharmacy Licensure

Provided Advice on Federal Price Reporting Requirements

Provided Advice and Counsel to Health Plan Client

Guidance to Health Care Company Addressing Allegation of Kickback

Provided Research Agreement Support

Provided General Health Care and Regulatory Advice

Provided Advice and Counsel to Hospital System

Counseled Health Insurance Agency on Medicaid Strategic Alliance

Advised System of Care in a Joint Venture

Recognition

- *The Best Lawyers in America*, Health Care Law (2017 to 2024)
- *Chambers USA: The World's Leading Lawyers for Business,* Massachusetts—Healthcare (2019 to 2023)
- *New England Rising Stars,* Health Care (2013 to 2019)

Credentials

Education

- University of Pennsylvania Law School (J.D., *cum laude*, 2008)
- University of Pennsylvania School of Medicine (M.BE., 2008)
- Bowdoin College (A.B., *magna cum laude*, 2002)
    - Phi Beta Kappa

Bar Admissions

- Massachusetts

Professional & Community Involvement

- American Health Lawyers Association
- Boston Bar Association

Focus Areas

Services

Academic and Clinical Research

Corporate Compliance Program Development, Implementation, and Effectiveness

Cross-Border Data Transfers

Drug and Medical Device Distribution

FDA Inspections and Enforcement

Fraud and Abuse Compliance Counseling and Defense

Government and Commercial Coding, Coverage, and Payment

Health Care

Industry Research and Clinical Trials

Life Sciences

Privacy Compliance Strategies

Privacy, Cybersecurity & Data Asset Management

Product Marketing and Compliance

Ransomware

Regulatory Strategy, Product Development, and Product Approvals

Stark and Self-Referral Laws

Value-Based Purchasing and Accountable Care

Industries

Academic Medical Centers

Health Care Industry

Hospitals and Health Systems

Life Sciences Industry

Medical Devices

Pharmaceuticals

Technology

Insights

FDA Issues Final Guidance on Informed Consent for IRBs, Clinical Investigators, and Sponsors
September 5, 2023

Epstein Becker Green Attorneys Recognized by 2024 *Best Lawyers* for Excellence in the Legal Profession
August 17, 2023

European Commission Adopts an Adequacy Decision for a New EU-U.S. Data Privacy Framework
July 12, 2023

FDA Issues Draft Recommendations for Implementing Decentralized Clinical Trials
June 2, 2023

Epstein Becker Green Recognized for Focused Excellence Across Core Practice Areas in *Chambers USA* 2023
June 1, 2023

Epstein Becker Green Attorneys Recognized by 2023 *Best Lawyers* for Excellence in the Legal Profession
August 18, 2022

Chambers USA 2022 Recognizes Epstein Becker Green's Focused Excellence in Core Practice Areas: Distinguished in Healthcare, Labor & Employment, and Litigation
June 1, 2022

Fifty-Eight Epstein Becker Green Attorneys Recognized for Professional Excellence–Three Attorneys Distinguished as "Lawyer of the Year"–by *The Best Lawyers in America* 2022
August 19, 2021

Ransomware: A Guide to Practical, Regulatory, and Reputational Risk Management
June 2, 2021

Epstein Becker Green's Focused Excellence Lauded by *Chambers USA* in 2021 Edition of Leading Law Firms and Attorneys
May 20, 2021