



Robert E. Wanerman

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ROBERT E. WANERMAN is a Member of the Firm in the Health Care and Life Sciences practice, in the Washington, DC, office of Epstein Becker Green. His practice concentrates on regulatory, reimbursement, and compliance matters affecting health care manufacturers, service providers, and investors in health care organizations. He has extensive experience counseling clients in matters arising under the Medicare and Medicaid programs, administrative law and procedure, the False Claims Act, clinical research rules, grant administration rules, the Anti-Kickback and Stark laws, HIPAA, and EMTALA. Mr. Wanerman was formerly an assistant counsel at the U.S. Department of Health and Human Services.

Mr. Wanerman:

- Advises clients in connection with coverage, coding, and reimbursement for medical technologies under Medicare, Medicaid, and commercial health plans
- Provides counsel on administrative law issues affecting health care manufacturers, suppliers, and providers, and represents clients in administrative hearings and appeals
- Represents clients in government audits, investigations, and litigation arising under the Medicare and Medicaid programs and under the False Claims Act, including negotiating settlements and corporate integrity agreements
- Counsels manufacturers and providers on clinical research contracting and compliance
- Advises manufacturers and providers on regulatory and reimbursement matters affecting applications of artificial intelligence in health care
- Develops and implements compliance programs and policies for medical device and pharmaceutical manufacturers, hospitals, academic medical centers, and long-term care facilities

Mr. Wanerman is a guest lecturer on digital health law at Cornell Tech, and has lectured in the Discovery to Market Program at the Johns Hopkins Carey Business School. He regularly gives presentations at industry conferences and is consistently ranked by participants as a top speaker.

Outside of the office, Mr. Wanerman is board member and Past President of The Ivymount Corporation, the parent organization of The Ivymount School & Programs, which provides educational programs and therapeutic services to students with speech and language impairments, learning disabilities, health impairments, and autism spectrum disorders.

Publications:

- *Biotechnology Entrepreneurship: Starting, Managing, and Leading Biotech Companies, 2nd ed.*, 2020 (co-author of chapters on Biotechnology Product Coverage, Coding, and Reimbursement Strategies and Artificial Intelligence in *Biotechnology: A Framework for Commercialization*)
- *Pharmaceutical and Medical Device Compliance Manual, 2nd ed.* 2019 (co-author of a chapter on coverage and reimbursement)
- *CMS Coverage Decision May Raise Barriers to Precision Cancer Medicine and Reduce Incentives for Evidence Development*, Health Affairs Blog, 2018
- *Pharmaceutical and Medical Device Law: Regulation of Research, Development, and Marketing, 2nd ed.*, 2015 (co-author of chapters on Federal Regulation of Clinical Research and Avoiding Fraud and Abuse Penalties and Sanctions)
- *Biotechnology Entrepreneurship: Starting, Managing, and Leading Biotech Companies*, 2014 (co-author of a chapter on Biotechnology Product Coverage, Coding, and Reimbursement Strategies)
- *Clinical Research Compliance Manual*, 2006 (co-author of chapter on Human Subject Protections in Clinical Research)
- *Clinical Research: Federal Rules and Regulations Manual*, 2002
- *The Basics of Coverage, Coding, and Reimbursement*, Journal of Commercial Biotechnology, 2012
- *It Ain't Over Till It's Over: Rights and Obligations When a Clinical Trial Ends*, 5 BNA Medical Research Law & Policy Report 439, 2006
- *HHS Proposes New Research Misconduct Procedures*, 3 BNA Medical Research Law & Policy Report 536, 2004
- *The EMTALA Paradox*, Annals of Emergency Medicine, 2002;40:464-69, 2002
- *OHRP Clinical Trial Oversight Guidance Fosters IRB Introspection, Policy Changes*, 1 BNA Medical Research Law & Policy Report 147, 2002
- *Hidden Fraud and Abuse Risks in Practice*, 50 AAOS Bulletin, December 2002
- *Conflicts of Interest in Biomedical Research: Managing Risks in an Imperfect World*, Food and Drug Law Institute Update, March/April 2002

Seminars:

- Reimbursement and Pricing Strategies, BIO International Convention, Biotechnology Entrepreneurship Boot Camp, 2011 – present
- Innovator Meets Regulator: The Challenge for Artificial Intelligence in Biotech, Biotech Week Boston, 2019
- Coverage, Coding, and Payment for Procedures, Devices, Drugs, and Diagnostics, Johns Hopkins Carey Business School, 2011 – 2013
- Navigating the Regulatory Landscape for New Medical Devices, Association of University Technology Managers, 2014 – 2015
- Seton Hall University School of Law, U.S. Healthcare Compliance Certification Program, 2014 – 2015
- Billing Compliance Master Class, MAGI Clinical Research Conference, 2014
- Inside the OIG's Toolbox, MAGI Clinical Research Conference, 2009 – 2013
- Coverage, Coding, and Payment for Devices, Drugs, and Diagnostics: Taking Your Product to Market, American University Washington College of Law Health Law and Policy Institute, 2008 and 2011
- U.S. Drug and Device Commercialization Issues: Coverage, Coding, and Payment, ILSI-Biomed (Israel), 2007 – 2008
- An Overview of Federal Health Care Programs for Drug and Device Manufacturers, Seton Hall Health Care Compliance Certification Program, 2008
- Coverage, Coding and Reimbursement in the U.S., Health Care Technological Innovation: From Idea to Commercialization, Tel Aviv University Faculty of Management, 2007
- Current Issues With The Medicare Modernization Act, Seton Hall Health Care Compliance Certification Program, 2007
- Negotiating and Drafting Clinical Trial Agreements, Health Care Compliance Association Research Compliance Conference, 2004
- Paying for New Cardiac Marker Tests: If You Build It, What Will They Pay?, 26th Annual Arnold O. Beckman Conference, American Association for Clinical Chemistry, 2004
- Clinical Research Compliance, American Health Lawyers Fraud & Compliance Forum, 2003
- Medicare Appeals from A to B, American Health Care Association Annual Meeting, 2003
- The Emergency Medical Treatment and Active Labor Act, George Washington University Department of Emergency Medicine Grand Rounds, 2003
- Current Legal Pitfalls in Orthopaedic Practice, American Academy of Orthopaedic Surgeons Annual Meeting, 2002
- Government Regulation Update, Health Care Financial Management Association, 2001
- Examination of a Research Compliance Plan: Is It Healthy?, Medical Research Summit, 2001

Education

- Columbia University (M.P.H., 1995)
 - School of Public Health
- New York Law School (J.D., 1985)
- University of Chicago (A.B., 1979)
 - Economics
- University of Chicago (Certificate in Healthcare Informatics, 2019)

Court Admissions

- Supreme Court of the United States
- U.S. Court of Appeals for the District of Columbia Circuit
- U.S. Court of Appeals for the First Circuit
- U.S. Court of Appeals for the Second Circuit
- U.S. Court of Appeals for the Tenth Circuit
- U.S. District Court, District of Columbia
- U.S. District Court, Eastern District of New York
- U.S. District Court, Northern District of New York
- U.S. District Court, Southern District of New York
- U.S. District Court, Western District of Pennsylvania

Bar Admissions

- District of Columbia
- New York

Practice Areas

- Behavioral Health
- Compliance Counseling and Defense
- Food and Drug Law
- Fraud and Abuse Counseling and Defense
- Government and Commercial Reimbursement
- Government Investigations and Litigation
- Value-Based Purchasing and Accountable Care

Industries

- Health Care and Life Sciences Industry

- Investment Banks & Private Equity
- Life Sciences Industry
- Medical Devices and Combination Products
- Pharmaceuticals

Memberships

- American Health Lawyers Association
- *Journal of Commercial Biotechnology*, Editorial Advisory Board