



John S. Linehan

Member of the Firm

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JOHN “JACK” S. LINEHAN is a Member of the Firm in the Health Care and Life Sciences practice, in the Baltimore and Washington, DC, offices of Epstein Becker Green. His practice focuses on pharmacy law, drug distribution and reimbursement, and related fraud and abuse issues, government investigations, and litigation matters.

Mr. Linehan:

- Counsels retail and specialty pharmacies, drug manufacturers and distributors, pharmacy benefit managers (PBMs), insurers, and other health care providers and suppliers on a range of pharmacy law and drug distribution issues, including pharmacy licensure and regulation; drug reimbursement by private insurers and under the federal health care programs; compounding, repackaging, and physician dispensing; contract disputes between PBMs and pharmacies; co-pay coupon, direct-to-patient sales, and patient assistance programs (PAPs); channel and formulary management strategies; and the structuring of specialty pharmacy distribution arrangements
- Provides regulatory and compliance advice relating to business entity formation and due diligence reviews of pharmacies and other drug suppliers and providers targeted in corporate mergers and acquisitions
- Serves as defense counsel in criminal and civil investigations and enforcement actions involving the U.S. Department of Justice (DOJ) and the Office of Inspector General (OIG) of the Department of Health and Human Services under the False Claims Act, the Anti-Kickback Statute, and the Food, Drug, and Cosmetic Act

Prior to joining Epstein Becker Green, Mr. Linehan served as a Special Assistant U.S. Attorney in the U.S. Attorney's Office for the District of Maryland and as a Law Clerk for the Honorable Richard D. Bennett of the U.S. District Court for the District of Maryland. He has been selected to the *Maryland Rising Stars* list (2017) in the area of Health Law.

Representative Matters

- Counseled various drug manufacturers on structuring specialty pharmacy arrangements in compliance with applicable federal fraud and abuse laws
- Provided strategic and legal advice to a drug manufacturer on a range of Medicare Part D issues, including exceptions and appeals processes, beneficiary protection provisions, formulary design, and annual CMS Call Letter guidance
- Represented a pharmacy in a breach-of-contract dispute with a drug wholesaler over drug pricing issues and in a dispute with a PBM relating to drug coverage and reimbursement for ultra-orphan drugs under state Medicaid managed care programs
- Provided strategic and legal advice to an insurer concerning cost-containment methods in providing pharmacy benefits under state workers compensation programs
- Advised a drug and device manufacturer on compliance and business risks associated with drug co-pay coupon programs
- Defended a health care supplier in *qui tam* False Claims Act allegations relating to Medicare Advantage risk adjustments
- Counseled an independent pharmacy and device supplier on a range of legal issues relating to state licensure, retailer rewards programs, and sales and marketing arrangements
- Defended a health care provider against criminal drug misbranding charges under the Food, Drug, and Cosmetic Act
- Advised a drug manufacturer on legal and business strategies relating to reimbursement for vaccines by private insurers and the federal and state health care programs
- Advised a trade association on a range of issues under Medicare Part D and the VA federal supply schedule (FSS) program

Select Publications & Speaking Engagements

- Panelist, *Compliance Issues in Contracting with Specialty Pharmacies and HUBs*, 17th Annual Pharmaceutical Compliance Congress and Best Practices Forum (Oct. 2016)
- Author, *Specialty Drug Copay Coupons: Despite Patient Benefits, Compliance Issues Persist*, Specialty Pharmacy Times (June 2016)
- Panelist, *Emerging Enforcement Issues Involving Managed Markets Activities*, Pharmaceutical Summit on Business & Compliance Issues in Managed Markets (June 2016)
- Author, *Drug Compounding: Cause and Cure for High Drug Prices?*, PharmExec.com (Mar. 2016)
- Author, *Taking Stock of Compliance Issues Impacting Specialty Pharmacy Arrangements*, Specialty Pharmacy Times (Feb. 2016)

- Author, *California Imposes Controversial Cost-Sharing Restrictions to Facilitate Patient Access to Expensive Drugs*, Health Care and Life Sciences Client Alert (Dec. 2015)
- Panelist, *The Pharmacist Will See You Now*, American Bar Association's 13th Annual Washington Health Law Summit (Dec. 2015)
- Moderator, *Structuring Specialty Pharmacy Distribution Arrangements in a Turbulent Regulatory Environment*, 16th Annual Pharmaceutical Compliance Congress and Best Practices Forum (Oct. 2015)
- Co-Author, *FDA Signals Tougher Approach to Animal Drug Compounding*, Law360 (June 2015)
- Author, *The Legal Implications of Pharmacist Provider Status and the Transformation of an Industry*, AHLA Connections (Nov. 2014)
- Speaker, *The Legal Implications of Pharmacist Provider Status: The Past, Present, and Future of a Transformative Movement*, American Society of Pharmacy Law 2014 Developments in Pharmacy Law (Nov. 2014)

Education

- University of Virginia School of Law (J.D.)
- Williams College (B.A., cum laude)

Bar Admissions

- District of Columbia
- Maryland
- New York

Practice Areas

- Food and Drug Law
- Fraud and Abuse Counseling and Defense
- Government and Commercial Reimbursement
- Government Investigations and Litigation
- Managed Care

Industries

- Health Care and Life Sciences Industry
- Pharmaceuticals
- Pharmacies

Court Admissions

- Maryland Court of Appeals
- U.S. Court of Appeals for the Fourth Circuit
- U.S. District Court, District of Maryland

Memberships

- American Health Lawyers Association
- American Society of Pharmacy Law