

Lee H. Rosebush

Partner

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Services

- FDA, Products Promotion, and Defense
- Pharmacy and Reimbursement
- Mergers and Acquisitions

Industries

- Healthcare Industry
- Life Sciences

Prior Positions

- Associate in the healthcare group of a national law firm.
- Pharmacist in hospital and national retail pharmacy settings in Indiana and Ohio.
- Gained regulatory experience during time at a *FORTUNE* 500 drug company.
- U.S. Food and Drug Administration: Office of Orphan Products.

Admissions

- U.S. Supreme Court
- District of Columbia
- Illinois
- Connecticut

Education

- J.D., Case Western Reserve University School of Law
- Pharm.D., Purdue University
- M.S., Indiana University, Finance
- M.B.A., Indiana University

With a background as a defense, regulatory, and registered patent attorney who has also worked as a registered pharmacist, Lee Rosebush provides his clients with legal counsel that is grounded in first-hand experience. Whether his clients are confronted with legal issues related to the naming of a drug, clinical trials, marketing, promotions, or advertising, Lee possesses a strong understanding of the pharmaceutical industry which, combined with his attention to detail and experience working with biologics, medical device, and healthcare companies, gives clients a single source for regulatory and litigation counsel. With post-graduate degrees in finance and business, Lee is frequently sought out to help expedite corporate deals involving healthcare entities. He also advises private equity and public and private companies in due diligence matters and buy-sell transactions.

Lee's ability to smoothly shift between the legal, governmental, and pharmaceutical environments further helps him to efficiently secure operating licenses or assist drug manufacturers avoid compliance actions from governmental agencies. Active with the Drug Quality and Security Act (DQSA), as well as the Federal Food and Drug Administration's (FDA) regulation of pharmacy compounding, Lee speaks and writes on both issues, and is passionate about orchestrating and advocating for pharmacists and pharmacies. Additionally, Lee is Leader of BakerHostetler's Pharmacy and Reimbursement team and Co-Leader of the FDA, Products Promotion, and Defense team.

Experience

- Lee represented a mail order pharmacy in its sale of stock to a pair of private equity groups.
- Lee represented a residential treatment center in an administrative Formal Hearing involving an alleged \$1.1 million Medicaid overpayment and obtained an outcome in favor of his client.
- Lee advised private equity groups specializing in the healthcare industry in a stock purchase of worker compensation specialty pharmacy.
- Lee represented a mail order pharmacy during a DEA and State Board of Pharmacy investigation into the company's controlled substance dispensing and record keeping practices.
- Lee provides ongoing counseling to a large national multifacility

healthcare system on the system's 340B practices.

- Lee assisted several entities with establishing a compounding entity and registering it with the FDA as a 503B Outsourcing Facility.
- Lee represented a large mail order pharmacy in its negotiations with DEA involving DEA's constructive delivery/transfer national policy position.
- Lee provides ongoing counseling to a large national health plan on strategic initiatives.
- Lee advised both drug manufacturers and healthcare entities on FDA's regulation of the importation of prescription drugs.
- Lee represented a Medicare Part D Plan in its acquisition of a PBM and several resulting regulatory matters.
- Lee provides ongoing counseling to a car manufacturer in its review of the manufacturer's advertising policies in light of FTC regulation.
- Lee advised a dietary supplement distributor during its review of the company's advertising SOPs.

Recognition

- Chambers USA: Recognized Practitioner: Healthcare: Pharmaceutical/Medical Products Regulatory in the District of Columbia (2016)
- Law360 "Rising Star" in Life Sciences (2015)
- Certificate of Appreciation by the FDA in recognition of outstanding contributions to the Office of Orphan Products Development (2004)

Memberships

- Food and Drug Law Institute (FDLI): Drugs Committee (2015 to 2018)
- Parenteral Drug Association: Member
- American Society for Pharmacy Law: Sponsorship Committee