FOLEY & LARDNER LLP

David L. Rosen

Partner

drosen@foley.com

Washington, D.C.
202.672.5430

With backgrounds in pharmacy and law, and 14 years of regulatory experience at the Food and Drug Administration (FDA), clients rely on David Rosen's nearly five decades of knowledge when seeking strategic guidance on FDA submissions, compliance, advertising, and enforcement.

A partner and public policy lawyer with Foley & Lardner LLP in the firm's Washington, D.C. office, David has extensive experience in health law, life sciences, and food and drug regulation, including a range of FDA regulatory issues affecting prescription and over-the-counter pharmaceuticals, medical devices, and biologics. He is the firm's FDA Practice Group leader, and member of the Government Solutions Practice Group, the Cannabis and Food & Beverage Industries, and the Health Care & Life Sciences and Telemedicine Sectors.

At FDA, David progressed to various supervisory positions involving virtually all aspects related to the drug approval process, combination products, jurisdictional issues, and related compliance activities. He authored the FDA's *Orange Book* (*Approved Drug Products With Therapeutic Equivalence Evaluations*), which identifies drug products approved by FDA on the basis of safety and effectiveness under the Federal Food, Drug, and Cosmetic Act; and was instrumental to the development and implementation of the Hatch-Waxman Act (the Drug Price Competition and Patent Term Restoration Act), as well as FDA's Accelerated Approval regulations for new drugs. He utilizes this insider perspective to assist clients within all FDA-regulated industries respond to warning letters and FDA 483 observations, write FDA meeting requests for pre-IND and 505(b)(2) products, and interact with FDA to facilitate product review and approval. He is a recognized leader in virtually all aspects related to the drug and medical device approval/clearance processes, combination products, and jurisdictional issues.

David frequently speaks before national and international pharmaceutical industry associations on the ANDA submission and review process and on the IND and expedited drug development, review, and approval processes. He has presented before investment analysts and managers of venture capital on the impact of FDA on the drug and biotech industry.

David was formerly a partner at two other major law firms where he was a member and leader of the FDA and life sciences practices.

Awards and Recognition

- Peer review rated as AV Preeminent®, the highest performance rating in the Martindale-Hubbell® Peer Review Ratings™ system
- *The Best Lawyers in America*® – FDA Law (2021-2024)
- *The Legal 500* – Life Sciences (2012-2016)
- IP Star, *Managing Intellectual Property* magazine (2015-2016)

Affiliations

- Emeritus member, University of Connecticut School of Pharmacy Advisory Board

Presentations and Publications

- Co-Author, "Health Care & Life Sciences Sector Top Trends for 2023," *Health Care Law Today* (Feb. 24, 2023)
- Co-Author, "Modernization of Cosmetics Regulation Act of 2022: What You Need to Know," *Health Care Law Today* (Jan. 25, 2023)
- Co-Author, "Psychedelic Drugs – Easing the Regulatory Hurdles for Development," *Health Care Law Today* (Dec. 15, 2022)
- Co-Author, "Hearing Aids: More Accessible to Consumers After FDA Issues Final Rule," *Health Care Law Today* (Aug. 17, 2022)
- Co-Author, "On the Attack: FDA Pursues Online Retail Fulfillment House," *Health Care Law Today* (Aug. 16, 2022)
- Co-Author, "Will FDA's Proposed Ban on Flavored Tobacco Products Ever be Implemented?," *Health Care Law Today* (May 26, 2022)
- Co-Author, "Vaping Will Not Make You Well," *Health Care Law Today* (Dec. 23, 2021)
- Co-Author, "The Proposed Cures 2.0 Act – What You Can Expect," *Health Care Law Today* (Dec. 6, 2021)
- Co-Author, "Is the DEA Poised to Regulate Telepharmacy?," *Health Care Law Today* (Nov. 30, 2021)
- Co-Author, "Round Two – FDA Issues Emergency Use Authorization for Moderna's COVID-19 Vaccine," *Coronavirus Resource Center: Back to Business* (Dec. 21, 2020)
- Co-Author, "FDA Issues Emergency Use Authorization for Pfizer-BioNTech COVID-19 Vaccine," *Coronavirus Resource Center: Back to Business* (Dec. 14, 2020)
- Co-Author, "Historic FDA Advisory Committee Vote on Pfizer and BioNTech's COVID-19 Vaccine," *Coronavirus Resource Center: Back to Business* (Dec. 10, 2020)
- Co-Author, "What You Need to Know About President Trump's Executive Order to Strengthen the Domestic Supply Chain for Essential Drugs and Medical Devices," *Coronavirus Resource Center: Back to Business* (Sept. 8, 2020)

- Co-Author, “COVID-19: FDA Issues Template for Over-the-Counter At-Home Testing,” *Health Care Law Today* (July 30, 2020)
- Co-Author, “FDA Increases Scrutiny of COVID-19 Serology Tests: What Commercial Manufacturers Need to Know,” *Coronavirus Resource Center: Back to Business* (May 6, 2020)
- Co-Author, “FDA Publishes Enforcement Policies to Address Coronavirus Personal Protective Equipment Shortages,” *Coronavirus Resource Center: Back to Business* (April 6, 2020)
- Co-Author, “Managing the Commercial Impact of the Coronavirus: FAQs for the Life Science Industry,” *Coronavirus Resource Center: Back to Business* (March 17, 2020)
- Co-Author, “DOJ Issues Guidelines for Enforcement Related to Off-Label Promotion,” *Legal News: Government Enforcement Defense & Investigations* (March 5, 2018)

Sectors

- Cannabis
- Food & Beverage
- Food Regulatory Compliance
- Health Care & Life Sciences
- Pharmaceuticals
- Racial Justice & Equity

Practice Areas

- Corporate
- Direct Selling & Multi-Level Marketing
- FDA Regulatory
- Government Solutions
- Israel

Education

- Catholic University of America (J.D.)

Admissions

- District of Columbia
- Maryland