HINSHAW

Life Sciences & Pharmaceuticals

Regulatory Strategy for Innovators in Drug Development, Distribution, and Care

Life sciences and pharmaceutical companies face intense scrutiny at every stage of the regulatory lifecycle. Companies must address FDA approvals, DEA oversight, state licensing, and multistate distribution with legal counsel that understands both the science behind the product and the operational demands of highly regulated markets.

At Hinshaw, we represent manufacturers, wholesalers, outsourcing facilities, specialty pharmacies, and healthcare innovators across the pharmaceutical and life sciences spectrum. Our attorneys provide practical guidance on FDA and DEA compliance, product development strategy, labeling and promotion, privacy, licensing, and investigations. Whether bringing a breakthrough therapy to market or responding to a regulatory inquiry, we deliver clear, coordinated counsel that helps protect innovation and reduce risk.

Deep Regulatory Insight Across Agencies and Jurisdictions: We help clients navigate the complex regulatory structures that govern drug and device development, including compliance with the FDA, DEA, state boards of pharmacy, and other federal and state enforcement bodies. Our advice reflects the latest agency guidance and enforcement trends, delivered in a business-first, operationally grounded way.

Support Across the Lifecycle of a Product or Facility: We advise life sciences clients from pre-approval research through market entry, expansion, and post-market surveillance. Whether structuring clinical trial relationships or responding to licensing board scrutiny, we provide holistic, responsive support.

Practical, Cross-Disciplinary Counsel: Our team works across health care regulation, corporate transactions, litigation, and privacy, helping life sciences and pharmaceutical clients manage compliance, structure partnerships, and defend against regulatory and civil risk.

Areas of Focus

Compounding Pharmacies & Outsourcing Facilities (503A/503B)

Counsel on sterile and non-sterile compounding, outsourcing facility registration, FDA guidance, USP standards, and multistate licensing compliance.

DEA & Controlled Substance Oversight

Supporting clients in registration, recordkeeping, security, and audit response under DEA rules for manufacturers, distributors, and registrants.

FDA Regulatory & Clinical Trial Compliance

Advising on IND and NDA processes, sponsor-investigator relationships, trial protocol development, adverse event reporting, and informed consent requirements.

Investigations & Enforcement Defense

Representation in FDA Warning Letters, Form 483 responses, board of pharmacy actions, civil investigative demands, and whistleblower claims under the False Claims Act.

Licensing & Multistate Operations

Supporting state licensing, change-of-ownership filings, wholesaler and third-party logistics provider (3PL) registrations, and interstate pharmacy operations.

Pricing, Reimbursement & Distribution

Advising on transparency laws, pricing reporting obligations, PBM contract strategy, and downstream pharmacy and provider integration.

Privacy & Data Governance

HIPAA, HITECH, and state data privacy counsel for companies collecting or using patient or clinical trial data, including breach response and cross-border concerns.

Learn More >

Product Labeling, Marketing & Promotion

Guidance on prescription drug advertising, labeling compliance, off-label communication risk, and enforcement trends under the FDCA and Lanham Act.

Advancing Science with Compliance at the Core

Life sciences and pharmaceutical companies operate at the intersection of innovation and oversight. At Hinshaw, we help clients navigate that intersection with clarity and confidence—offering integrated legal support that scales with your business and keeps pace with your science. Whether you're advancing clinical research, scaling distribution, or defending against regulatory scrutiny, we deliver counsel designed to protect what you're building and power what's next.

Insights

Healthcare Alert
Oct 29, 2025

California Senate Bill 41 Reshapes PBM Rules: What Pharmacies Must Do Now

In The News
Oct 10, 2025

Michael Dowell Analyzes How Telepharmacy is Combating Pharmacy Closures and Improving Health Equity

Healthcare Alert
Jun 30, 2025

OIG Advisory Opinion 25-03: Navigating Anti-Kickback Rules and Safe Harbors in Telehealth Contractual Arrangements

Healthcare Alert
Apr 24, 2025

Beyond the Glow: Key Medical Spa Compliance Challenges and Legal Pitfalls

Healthcare Alert
Sep 5, 2024

Don't Jeopardize Your License: Ensure Compliance With California State Board of Pharmacy Notification and Reporting Obligations

Press Release
May 15, 2024

Hinshaw Expands Health Care Practice on East Coast

Press Release
Mar 4, 2024

Scott Seaman Recognized as a Top Insurance Author in JD Supra 2024 Readers' Choice Awards

Healthcare Alert
Dec 15, 2023

California Prohibits PBM Discriminatory Practices Against 340B Program Covered Entities and Contract Pharmacies

Healthcare Alert
Nov 17, 2023

California Expands “No Pharmacist Left Alone” Pharmacy Staffing Requirements and Also Enacts New Safety Measures

In The News
Dec 8, 2022

Michael Dowell Discusses Impact on Pharmacies of U.S. Supreme Court Ruling that DEA Must Prove Knowing and Intentional Violations of the CSA

Press Release
Nov 21, 2022

Michael Dowell Recognized as a Top Health Care Lawyer by The Daily Journal

In The News
Sep 13, 2022

Michael Dowell Discusses State Regulatory Scrutiny of Pharmacy Benefit Managers

To Find Out More Contact

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Related Capabilities

Commercial Finance

Complex Tort & General Casualty

Corporate & Transactions

Data Privacy, AI & Cybersecurity

Healthcare

Healthcare Regulation, Compliance & Licensing

Healthcare Transactions

Insurance

Intellectual Property

Litigation & Trial

Manufacturing

Regulatory & Compliance