Hogan Lovells

Michael N. Druckman

Partner

Washington, D.C.

Phone

+1 202 637 5600

Fax

+1 202 637 5910

Email

mike.druckman@hoganlovells.com

Biography

Mike Druckman leverages his prior experience at the FDA – and what he has learned since then while extricating companies from regulatory problems – to anticipate and prevent life science clients from getting into trouble in the first place.

Mike understands the business challenges that companies face in a highly regulated environment. He actively works with other Hogan Lovells lawyers experienced with government reimbursement, anti-kickback limits, product liability, and a full range of other regulatory areas to craft approaches that will maximize clients' opportunities and minimize their risks.

Mike chairs the firm's Cell, Tissue, and Gene Therapies Working Group, a cross-disciplinary team that advises companies in this emerging space on the evolving regulatory and business challenges they face. Mike and the team work closely with companies developing stem cells, cord blood, placental tissues, gene therapies, proteins, and other cellular products to help people with serious health problems.

Mike also advises companies with a full range of regulatory challenges involved in investigating new drugs, biologics, and combination products, obtaining FDA approval for those products, and in promoting, selling, and distributing them. His experience also includes the Drug Supply Chain Security Act, pharmacy

Practices

Pharmaceuticals and Biotechnology Regulatory

Industries

Life Sciences and Health Care

Areas of focus

Product Development and Approval

Cell, Tissue, and Gene Therapies

Clinical Trials

Transaction and Securities Disclosure Support and Due Diligence

Regulatory Exclusivities, Hatch-Waxman, and Similar Statutes

compounding, expanded access/compassionate use clinical trials, orphan drug exclusivity, and precision medicine and companion diagnostics.

While in the FDA Office of the Chief Counsel, Mike also advised on medical countermeasures. He served on the FDA's Pandemic Influenza Planning and Preparedness Team, and helped draft guidance on pandemic and seasonal flu vaccines and a regulation on Strategic National Stockpile product labeling. In his years at the firm, Mike has advised on Emergency Use Authorizations, select agents and toxins and Dual Use Research of Concern (DURC), and various issues involving vaccines and other products.

Representative experience

Helped obtain orphan drug designation for a vaccine.

Guided a company in bringing a blood derivative back to market after a complete recall.

Helped prevail on a Prescription Drug User Fee Act (PDUFA) fee dispute with the FDA.

Crafted stem cell legislation and regulations.

Worked with the FDA and colleagues in Government Contracts group to ensure that a tissue company's products remained on the Federal Supply Schedule.

Helped convince the FDA to change a long-standing policy, increasing incentives for innovative drug combinations.

Helped win two formal dispute resolutions, allowing the client to market a new drug formulation with a new brand name under a separate NDA.

Awards and rankings

- FDA Commissioner’s Special Citation, Pandemic Influenza Planning and Preparedness Team, 2007
- Secretary’s Award for Distinguished Service, Influenza Vaccine Shortage Response Team, 2004

Latest thinking and events

Pharmaceuticals and Biotechnology

Education and admissions

Education

J.D., University of Pennsylvania Law School, 1990

A.B., Harvard College, magna cum laude, 1987

Bar admissions and qualifications

District of Columbia

- News
  - FDA invites comments on xenotransplantation product regulatory standards ahead of public meeting
- Hogan Lovells Podcasts
  - Podcast: Talking the cure
- News
  - Time’s really up! FDA authority to crack down on regenerative medicines upheld as grace period ends
- News
  - Time’s up: New enforcement era for regenerative medicines begins June 1
- News
  - Life sciences and health care horizons 2021
- News
  - FDA extends enforcement discretion period for regenerative medicines, citing COVID-19 challenges