Christopher M. Mikson, M.D.

Partner

christopher.mikson@dlapiper.com

Philadelphia
T: +1 215 656 3380
F: +1 215 606 2075

Washington, DC
T: +1 202 799 4000
F: +1 202 799 5000

Chris is a medical doctor, registered patent attorney, and seasoned litigator who advises and represents clients in Food and Drug Administration regulatory matters and complex litigation and transactional matters involving healthcare and the life sciences.

Regulatory: Chris has extensive experience in the regulation of drugs, biologics, human cell and tissue products (HCT/Ps), and medical devices by FDA and other federal and state agencies. He has counseled and represented clients in regulatory matters across all stages of the product life cycle, from research and development to nonclinical testing, clinical trials, premarket clearance and approval, manufacturing and distribution compliance, and post-market surveillance and reporting, including a broad range of agency proceedings such as Orange Book listing disputes, comments during rulemaking, citizen petitions, establishment inspections, responses to agency letters, and enforcement actions. Chris has completed FDA's Clinical Investigator Training and NIH's Clinical Research Training, affording him a multi-disciplinary understanding of current and evolving regulatory conditions as well as state-of-the-art science and technology that are critical to the design, conduct, and ultimate success of clinical trials for small molecule drugs, biologics, HCT/Ps, and medical devices.

Litigation and Transactional: Chris has comprehensive experience in a broad range of complex litigation matters. He has represented some of the world's largest pharmaceutical, medical device, consumer product, and technology companies in patent infringement, trade secret, false advertising, and product liability litigation. Chris focuses his litigation practice on FDA regulatory disputes and cases where FDA regulation intersects with other areas of the law, such as product liability and intellectual property, including Hatch-Waxman and biosimilar cases. In addition to his litigation practice, Chris regularly performs transactional work related to FDA-regulated products, including material and service contracts, licensing agreements, and due diligence of major deals.

RELATED SERVICES

- Litigation, Arbitration and Investigations
- Intellectual Property and Technology
- FDA
- Product Liability, Mass Torts and Product Stewardship

RELATED SECTORS

- Life Sciences
- Healthcare

CREDENTIALS

Admissions

- District of Columbia
- New Jersey
- Pennsylvania
- United States Patent and Trademark Office

Recognitions

LMG Life Sciences recognized Chris as a "Life Sciences Star" since 2018.

Education

- M.D., Jefferson Medical College
- Post-Baccalaureate Premedical Program, University of Pennsylvania
- J.D., Rutgers University School of Law
  Articles Editor, *Rutgers Law Journal*
- B.A., Rutgers College

Courts

- Supreme Court of the United States
- United States Court of Appeals for the Federal Circuit
- United States Court of Appeals for the Third Circuit
- United States District Court for the District of New Jersey
- United States District Court for the Eastern District of Pennsylvania

Civic and Charitable

Chris has long served as a pro bono lawyer with the Support Center for Child Advocates, providing legal representation and social service advocacy for abused and neglected children in Philadelphia.

INSIGHTS

Publications

[UPDATED] As device industry veterans and newcomers step up to the line, FDA swiftly adjusts regulatory hurdles for personal protective equipment during the COVID-19 pandemic

6 April 2020
A high level overview of the FDA's tiered, risk-based approach to masks, face shields and respirators based on developments to date.

Potential paths forward amidst the challenges to COVID-19 therapeutic and vaccine development; collaboration and communication among clinical trial stakeholders takes on heightened importance (United States)

20 March 2020

In a March 19, 2020, briefing and press release, the US Food and Drug Administration outlined ways that existing regulatory options may make it possible to expedite access to therapeutics and vaccines with the potential to treat or prevent coronavirus disease 2019 (COVID-19).

Events

Chris has spoken and written extensively on intellectual property and regulatory issues, including those concerning Hatch-Waxman, biosimilars, and medical devices. He has taught patent and FDA law at the University of Pennsylvania and regularly provides training on drug and device regulation for new hires at FDA as well as major drug and device companies.

NEWS

DLA Piper advises Arlington Capital Partners in majority investment in Everest Clinical Research Corporation

21 December 2020
DLA Piper represented Washington, DC-based private equity firm Arlington Capital Partners in its investment in Everest Clinical Research Corporation, a leading contract research organization providing a comprehensive suite of mission-critical clinical research services to the worldwide pharmaceutical, biotechnology and medical device industries across Phase I-IV trials.

Christopher Mikson joins DLA Piper's Litigation practice in Philadelphia and Washington, DC

23 January 2020

DLA Piper announced today that Christopher Mikson has joined the firm’s Litigation practice as a partner in Philadelphia and Washington, DC.