



**Christopher M. Mikson M.D.**

**Partner**

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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.

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

## 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.

For more information, pursuant to New Jersey Lawyer Advertising guidance, please [click here](#).

## 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

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### Publications

#### **Hear ye, hear ye! FDA finalizes OTC hearing aids rule and issues updated guidance on personal sound amplification products**

6 September 2022

A paradigm shift for the hearing aid industry and patients.

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### 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

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**DLA Piper represents Intercept Pharmaceuticals, Inc. in US\$450 million deal to sell Ocaliva to Advanz Pharma outside the US**

6 May 2022

DLA Piper is representing Intercept Pharmaceuticals, Inc. (Nasdaq: ICPT) – a biopharmaceutical company focused on the development and commercialization of novel therapeutics to treat progressive non-viral liver diseases – in its deal to sublicense to Advanz Pharma the rights to commercialize Ocaliva® (obeticholic acid) outside of the US, and sell certain foreign subsidiaries and rights regarding Intercept's international operations.

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**DLA Piper advises Axsome Therapeutics in its acquisition of Sunosi from Jazz Pharmaceuticals**

13 April 2022

DLA Piper represented Axsome Therapeutics in connection with its acquisition of Sunosi from Jazz Pharmaceuticals.

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**DLA Piper advises Haymaker Acquisition Corp. III in business combination with BioTE Holdings, LLC**

13 December 2021

DLA Piper represented Haymaker Acquisition Corp. III, a special purpose acquisition company, in its business combination with BioTE Holdings, LLC (Biote), a high-growth, differentiated medical practice-building business within the hormone optimization space. Upon closing, the combined company's Class A common stock is expected to be traded on the Nasdaq Stock Market under the symbol "BTMD."

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**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.

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