Hogan Lovells

Jason F. Conaty

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Biography

With over seven years of immersive lawyering in the FDA regulatory arena, Jason Conaty works with pharma and biotech companies to solve the myriad of problems they face in the often decades-long struggle to bring innovative new medicines from the laboratory bench, into the clinic, and on into the marketplace. Jason helps these companies navigate the thicket of laws and regulations that lie between the discovery of an important new drug, and the patient who needs it.

Before heading to law school, Jason was a bench scientist, working and publishing in the field of nucleic acid chemistry and rational drug design. He completed his Ph.D. in Australia before settling in the United States to take a position at Massachusetts General Hospital, where he was a Fellow of the Leukemia and Lymphoma Society, and a Fellow in Genetics at Harvard Medical School.

As a scientist and a lawyer, Jason has advised and advocated on countless scientific and regulatory matters in the life sciences and biotechnology space. Concentrating on the development, approval, and marketing of complex therapeutic products, Jason has deep experience on lifecycle management issues relating to drugs, biologics, and drug-device combination products.

Practices

Pharmaceuticals and Biotechnology Regulatory

Industries

Life Sciences and Health Care

Areas of focus

Pharmaceuticals and Biotechnology

Cell, Tissue, and Gene Therapies

Education and admissions

While at law school, Jason clerked for the United States Senate Judiciary Committee, in the office of Senator Edward M. Kennedy. He remains committed to prisoner rights and fair sentencing issues through his pro bono practice.

Representative experience

Advocated before FDA's Exclusivity Board regarding the application of marketing exclusivity to a newly approved product.

Solved a scientific impasse with FDA using the agency's Formal Dispute Resolution process, leading to the approval of a small company's drug product.

Advises a major pharma company on the implications of the BPCIA to its product pipeline.

Latest thinking and events

- News
  - FDA quietly withdraws plans for a Devices Referencing Drugs regulatory approval pathway
- News
  - HHS announces public meeting on ways to accelerate clinical innovation
- News
  - FDA guidance may ease path to biosimilar interchangeability *Focus On Regulation*
- Hogan Lovells Publications
  - FDA to consider patent listing, therapeutic equivalence, and other Orange Book issues; agency will issue draft guidance documents, seek public comment *Focus On Regulation*
- News
  - FDA mulls Orange Book overhaul to address patent listing, therapeutic equivalence, other issues
- Blog Post
  - FDA Guidance on Transition Biological Products:

Education

J.D., Georgetown University Law Center, cum laude, 2007

Ph.D. Biochemistry, University of New South Wales, Australia, 2000

B.S., University of Technology, Sydney, first class honors, 1995

Bar admissions and qualifications

District of Columbia

New York

Implications for Exclusivity and Patent Listings