Hogan Lovells

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Biography

Heidi Gertner works at the forefront of the drug regulatory industry. She provides insight to large and small pharmaceutical companies and research institutions in dealing with government regulators to maximize business potential.

With her wealth of drug regulatory knowledge and creative thinking skills, Heidi finds solutions to client problems and is a tireless advocate. She helps clients resolve their enforcement differences with the FDA and facilitates positive relationships with the agency. Heidi anticipates and helps clients dealing with cutting-edge issues, both by assessing policy initiatives and finding new business opportunities.

Heidi began her professional career with a focus on bioethics and law, completing two post-doctoral bioethics fellowships, one at the Cleveland Clinic Foundation, and another at the National Institutes of Health. At the National Institutes of Health, Heidi's work focused primarily on human subject protection and research ethics issues.

Heidi honed her legal skills at the FDA's Office of Chief Counsel, where she advised government regulators on almost all aspects of drug regulation for 13 years. At the FDA, Heidi's portfolio focused on drug advertising and promotion, combination products, drug safety, clinical

Practices

Administrative and Public Law

Marketing and Advertising

Pharmaceuticals and Biotechnology Regulatory

Industries

Life Sciences and Health Care

Areas of focus

Pharmaceuticals and Biotechnology

Clinical Trials

Cell, Tissue, and Gene Therapies

trials and human subject protection, Rx-OTC switches, and over-the-counter drug regulation. While at the agency, she oversaw numerous rulemaking and enforcement actions. As one of a handful of senior lawyers, Heidi worked closely with the Center for Drugs, HHS officials, and congressional staff.

Heidi joined Hogan Lovells in 2014 and calls the D.C. office her home base. She is plugged into the D.C. regulatory scene and works closely with companies and research institutions on developing regulatory and business strategy. She is an integral part of the skilled team of drug regulatory lawyers and works across numerous groups within the firm to provide clients with comprehensive legal and business advice. She is also an adjunct professor of law at American University's Washington College of Law, where she has challenged students in her Health Law Bioethics class for the past 15 years.

Representative experience

Represents major pharmaceutical companies in drug regulatory matters before FDA.

Resolves numerous human subject protection and clinical trial matters for clients.

Teaches law students the complex issues at the intersection of law and bioethics.

Awards and rankings

- Commissioner's Special Recognition Award, *FDA Commissioner's Award of Excellence*
- FDA Outstanding Service Award
- HHS Secretary's Award for Distinguished Service

Latest thinking and events

- News
  - FDA proposes annual summary reporting

Education and admissions

Education

J.D., Washington University in St. Louis School of Law, 1997

B.A., Binghamton University, cum laude, 1994

Memberships

Member, American Bar Association

Member, American Society of Bioethics & Humanities

Bar admissions and qualifications

District of Columbia

Maryland

requirements for Right to Try drug sponsors, manufacturers

- News
  - FDA quietly withdraws plans for a Devices Referencing Drugs regulatory approval pathway
- Webinar
  - Response to COVID-19 webinar series part V: Navigating clinical trials during the COVID-19 pandemic
- News
  - HHS offers flexibility on human subjects protection regs during COVID-19 pandemic
- Webinar
  - How landmark OTC drug reform legislation will affect your business
- News
  - At long last, landmark OTC Drug reform legislation is enacted