Bruce S. Manheim Jr.

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Bruce Manheim represents life science companies on a wide array of matters, including regulatory issues before the Food and Drug Administration and other agencies, life cycle management strategies for pharmaceuticals, GMP compliance matters, government and internal investigations, administrative agency litigation, valuation and diligence on life science transactions, and environmental compliance issues involving biotech products. Mr. Manheim has also developed special knowledge on issues surrounding research, development and commercialization of products under the Biodiversity Convention and Nagoya Protocol.

Mr. Manheim holds graduate degrees in both science and law, and brings a multidisciplinary approach to the complex issues at the forefront of today's life sciences industry. He also shares a special understanding of the manner in which in-house counsel grapple with issues confronting life science companies. He spent almost a year on a secondment as acting general counsel of a major business unit of a large medical device company. Mr. Manheim frequently counsels life science clients based outside of the United States on FDA regulatory issues and related matters.

Mr. Manheim has extensive experience representing clients on matters involving drugs, biologics, devices, cosmetics, supplements and other food products. Mr. Manheim assists clients on biosimilars and Hatch-Waxman exclusivity issues, leads internal investigations and compliance assessments, and works closely with attorneys from the Litigation/Controversy Department on civil and criminal investigations. He has filed numerous petitions with FDA and served as lead counsel in litigation challenging FDA and other federal agency actions.

Mr. Manheim was formerly a partner in the Life Sciences Group at Ropes & Gray for more than 10 years. Before that, he served as counsel and partner at a boutique FDA law firm for a decade. Prior to entering private practice, Mr. Manheim worked for many years as a senior attorney-scientist at the Environmental Defense Fund, where his practice focused on public health and environmental issues arising within both domestic and international legal frameworks.

Professional Activities

Since entering private practice, Mr. Manheim has continued to pursue his interest in *pro bono* matters involving significant public policy issues. He successfully represented the Brady Campaign to Prevent Gun Violence in a lawsuit striking down a federal rule that would have allowed loaded and concealed guns in national parks and wildlife refuges. (*Brady Campaign to Prevent Gun Violence v. Salazar*) He currently serves as co-lead counsel to the chapters of three national medical organizations in First Amendment litigation challenging a Florida law barring physicians from asking their patients about firearm safety. (*Wollschlaeger v. Farmer)*

Speaking Engagements

Mr. Manheim has recently made the following presentations:

- Nitrogen Fixation in Mexican Native Maize: A Success Story for Implementation of the Nagoya Protocol with Global Implication for Agriculture, *Side Event, Fourteenth Meeting of the Parties to the Biodiversity Convention and Nagoya Protocol* (November 2018)
- On September 12, 2018, Mr. Manheim spoke at the London School of Economics, which organized a symposium of international experts on “The Use and Circulation of Genetic Resources under Measures Implementing the Nagoya Protocol.” Mr. Manheim’s presentation was entitled “Negotiating Commercial Contracts under a Due Diligence Framework”
- The Nagoya Protocol and the Plant Treaty: A Practical Perspective to Compliance and the Development of ABS Agreements, Presentation at the ASHS 2015 Annual Conference, New Orleans, LA (August 2015)
- An Ounce of Prevention is Worth a Pound of Cure: Responding to the Government's Increased Reliance on the Park Doctrine and OIG Exclusion of Corporate Officers, Presentation at AdvaMed2011, Washington, (September 2011)
- Biosimilars: Building the Path Forward, Presentation at the FDA/CMS Summit, Washington, (December 2011)
  Biosimilars in Mergers, Licensing and Collaboration Arrangements, Presentation to the First C5 Forum, London (January 2012)
- U.S. FDA Regulation of Drugs and Biologics: Legal Overview and Case Studies, Presentation to the Korea Pharmaceutical Manufacturers Association, Seoul (April 2012)
- Reducing Regulatory Risks in Transactions: Key Actions and Best Practices, Presentation at the Deloitte Touche Tohmatsu Life Sciences Seminar, Tokyo (September 2012)
- Biosimilars in the United States: The Emerging Regulatory Framework, Presentation to the Japan Pharmaceutical Legal Affairs Association, Tokyo (September 2012)
- Utilizing the Biosimilar Approval Pathway to Gain Access to the World’s Most Lucrative

Pharmaceutical Market, Presentation to the Second C5 Forum, Munich (December 2012)

Solutions

- Crisis Management and Strategic Response
- Government and Regulatory Litigation
- Healthcare
- Life Sciences
- Litigation
- Public Policy and Legislative Affairs
- White Collar Defense and Investigations

Experience

FDA REGULATORY MATTERS

- Assisted a major biotechnology company with numerous legal and legislative issues surrounding the development and implementation of the biosimilars legislation.
- Submitted citizen petitions, and assisted in preparation for Advisory Committee meetings, on various issues involving approval of generic versions of complex products.

INVESTIGATIONS AND COMPLIANCE ASSESSMENTS

- Conducted an internal investigation of GMP and promotional issues surrounding a biologic product with black box warnings concerning immunogenicity.
- Assisted in the defense of the chairman of a medical device company in a government enforcement investigation involving allegations of improper marketing of devices.
- Led a post-acquisition investigation and analysis of a pharmaceutical company's marketing practices and compliance protocols.

TRANSACTIONAL ACTIVITIES

- Conducted diligence and prepare an evaluation of the value of a target company in connection with its acquisition by a large pharmaceutical firm.
- Counseled a large medical device company on various issues surrounding royalty agreements, consulting agreements and grant agreements.

BIODIVERSITY COMPLIANCE AUDITS

- Assisted a major pharmaceutical company on compliance issues and access-benefit sharing agreements arising under the Biodiversity Convention.
- Conducted a biodiversity compliance assessment of, and developed internal compliance procedures for, the research division of an international food and

nutrition company.

Recognition

- Selected by peers for inclusion in *Best Lawyers in America* for his work in FDA law (2014–2023).
- Named a "Life Sciences Star" by *LMG Life Sciences* (2020–2023).
- Recommended in the 2017 and 2018 editions of *The Legal 500 United States* for Healthcare: Life Sciences.
- Recognized in the 2012, 2013 and 2014 editions of *Chambers USA: America's Leading Lawyers for Business* for Healthcare: Pharmaceutical/Medical Products Regulatory.
- *National Law Journal* 2011 "Champion Award" for Upholding the Legal Profession's Core Values Through Public Service, *Pro Bono* Efforts and Advocacy for Civil Liberties.

Credentials

EDUCATION

JD, Georgetown University Law Center, 1988

cum laude

MSL, Public Policy, Vermont Law School, 1981

cum laude

MS, Claremont Graduate University, 1978

cum laude

BA, Biology, Pomona College, 1977

cum laude

Phi Beta Kappa

ADMISSIONS

District of Columbia

New York

California

US Court of Appeals for the First Circuit