ALSTON & BIRD

Marc J. Scheineson

Partner

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Marc is an FDA and congressional insider experienced in strategically resolving regulatory and legislative issues for product manufacturers using the legal levers available in Washington, D.C.

Marc Scheineson is a partner in the Washington, D.C. office, where he heads Alston & Bird's Food & Drug Law Team. He advises companies on a wide range of issues, including product approvals, marketing, clinical studies, and enforcement. Previously, he served as the associate commissioner under then-FDA Commissioner David Kessler for legislative affairs of the Food and Drug Administration. He was involved there in many agency innovations, including prescription drug user fees, debarment, medical device amendments, and nutritional labeling. He was also counsel to the ranking member of the Health Subcommittee of the House of Representatives Committee on Ways and Means, and a senior vice president of Ketchum Communications. Marc is also experienced with the application of the OIG anti-kickback statute, HIPAA privacy rules, patent term exclusivity, institutional review board regulation, human research protection, scientific misconduct, technology transfer and licensing, advertising and promotion law, and ACCME accreditation, and he advises on the FDA regulatory aspects of corporate acquisitions.

Marc has been recognized by *The Best Lawyers in America©* and *Chambers USA*, and he has been named a top-rated FDA lawyer in Washington, D.C. by *Super Lawyers*. In addition, he received the coveted AV Preeminent® Rating by the *Martindale-Hubbell* legal rating service based on a survey of his clients and peers.

Representative Experience

- Assisting FDA-regulated entities on emergency use authorization in relation to coronavirus test kits, hand sanitizers, and surgical masks.
- Represented a major pharmaceutical manufacturer in amending an analgesic over-the-counter drug monograph to recognize preventive cardiovascular uses of aspirin.
- Assisted in the preparation and advocacy of an orphan drug designation request for a biologic leukemia drug.
- Obtained an FDA Division of Drug Marketing, Advertising, and Communications (DDMAC) warning letter against the illegal marketing practices of the competitor manufacturer of the COX-2 inhibitor.
- Defended against a DDMAC investigation of the marketing practices of an MRI-MRA imaging contrast agent maker.
- Participated on company review committees for the launch and dissemination of promotional materials for a biologic arthritis drug and for collagen device dermal filler products.
- Performed regulatory due diligence for the acquisition of companies and products, including over-the-counter cough medicine, high-dose expectorant, infant formulas, multiple prescriptions and over-the-counter drug products, and heart monitoring devices.
- Led a legal and regulatory team to obtain the first FDA clearance of private-label infant formula.
- Negotiated an FDA good manufacturing practice consent decree for a catheter maker that preserved existing inventory.

- Assisted with the new drug application approval of the first levothyroxine product, and removed unapproved guaifenesin products.
- Represented a major national clinical research organization in FDA self-disclosure, inspection, and negotiations for remedial action.
- Led a litigation and regulatory team to preserve marketing rights for "grandfathered drug" products until FDA approvals could be obtained.
- Assisted in the review, revision, and acquisition by a major online medical information provider of an accredited continuing medical education sponsor.

Publications & Presentations

Publications

- "Regulation of Drugs, Biologics, Controlled Substances, Cannabis, and Compounded Drugs," in A Practical Guide to FDA's Food and Drug Law and Regulation, 7th ed., Food and Drug Law Institute, 2020.
- "Finding Common Ground on New FDA Regulatory Approach for Regenerative Cell Therapy," *Bipartisan Policy Center*, June 9, 2016.
- "Policy Options for Off-Label Communication: Supporting Better Information, Better Evidence, and Better Care," Duke-Margolis Center for Health Policy, February 2016.
- "The Media Has Been All Over 'Bad Pharma,' But Has the Department of Justice Followed Suit?" *Life Science Compliance Update U.S. Edition*, Vol. 1.2, April 2015.
- "FDA's Global Investigation and Enforcement Authority, Partnerships, and Priorities," in *Food and Drug Regulation in an Era of Globalized Markets*, Elsevier-Academic Press, 2015.

Presentations

- "FDA Under the Biden Administration: What's to Come and What It Will Mean," *FDANews,* webinar, February 10, 2021.

Professional & Community Engagement

- Food and Drug Law Journal, Editorial Advisory Board
- *Policy and Medicine Compliance Update*, Editorial Board
- American Bar Association (ABA) Committee on Food and Drug Law, former chair
- ABA Task Force on FDA Reform, former chair
- Food and Drug Law Institute (FDLI), Update Magazine Editorial Board, former member of Drug and Device Committees
- *FDANews Washington Drug Letter*, Editorial Advisory Board
- Bar Association of the District of Columbia, Young Lawyers Section, former chair
- In-House Training Team to FDA sponsored by FDLI
- Anti-Defamation League, Washington, D.C. Chapter, Executive Committee
- American-Israel Public Affairs Committee, Washington, D.C. Chapter, former board member
- University of Cincinnati Foundation, board
- University of Cincinnati College of Law Alumni Association, board

Education

- University of Cincinnati (J.D., 1980)
- Georgetown University (LL.M., 1987)
- University of Cincinnati (B.A., 1977)

Admitted to Practice

- District of Columbia
- Ohio

Related Services

Health Care | FDA/Food, Drug & Device | Corporate & Finance | Legislative & Public Policy | Health Care Legislative & Public Policy | HIPAA/Health Information Privacy, Security & Breach Response | Life Sciences | Biotechnology, Pharmaceutical & Life Sciences Patent Litigation | Food, Beverage & Agribusiness