Arent Fox

Arent Fox LLP
Attorneys

Deborah M. Shelton

FOOD, DRUG, MEDICAL DEVICE & COSMETIC GROUP LEADER

Deborah helps clients navigate complex regulations in the Life Sciences industry, with a specific emphasis on medical devices, biotechnology, and pharmaceuticals.

Industries

Prescription Drugs, Biologics & Diagnostics

Practices

Environmental, Social, and Corporate Governance (ESG)

Coronavirus (COVID-19) Task Force

Food, Drug, Medical Device & Cosmetic

Education

University of Maryland Francis King Carey School of Law JD, with honors

University of Maryland BS, summa cum laude

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Deborah has more than 20 years of experience as an FDA regulatory attorney, with a focus on medical devices, drugs, and biologics. In addition to representing clients in matters before FDA, Deborah advises clients in matters regulated by the DEA, FTC, and USDA. Her clients include companies of all sizes, from startup enterprises to multinational corporations, for whom she provides strategic counsel in navigating complex regulations that impact every stage of product development, approval, marketing, and the numerous other post-approval compliance issues. Deborah is a member of the firm's Prescription Drugs, Biologics and Diagnostics Industry Group.

Deborah also works closely with her corporate and health care colleagues to provide regulatory due diligence in transactional matters, and to provide regulatory counseling concerning the import and export of FDA-regulated products. She has represented clients in matters before state regulatory and legislative bodies as well as in administrative law proceedings, providing regulatory counsel and developing and advocating legal positions in support of her clients' business objectives. Deborah's strategic and pragmatic approach to client counseling is informed by her deep industry-relevant experience and from her several years of serving in key corporate counsel roles.

Deborah is agile and pragmatic and leverages those skills to work with clients on developing optimal regulatory strategies to navigate complex, cutting-edge issues. She frequently works with companies developing digital health technologies. Amidst shifting legal and policy issues and evolving changes in the FDA and related legal framework governing software as a medical device (SaMD) and other digital health products, Deborah provides regulatory advice to help clients bring their products to market and stay compliant with legal and regulatory requirements.

Deborah has extensive legislative and regulatory experience with biosimilars, including serving as the lead US attorney on the biosimilars team at a global biotech company successfully marketing both innovator and biosimilar products. Deborah's biosimilar expertise is a continuation of decades of work on matters in which patent and regulatory law intersect, including Hatch-Waxman and regulatory exclusivities such as new chemical entity, new clinical investigations, orphan drug, and pediatric. In this capacity, Deborah works closely with litigation colleagues to craft legal theories, arguments, and strategies in support of her clients' positions in Hatch-Waxman and other complex matters arising under the federal Food, Drug, and Cosmetic Act and related laws.

Actively engaged in evolving legislative and regulatory matters, Deborah also analyzes federal laws, regulations, and legislative proposals relevant to the cannabis industry and advises and engages in regulatory advocacy on behalf of clients seeking to enter the cannabis market.

Deborah works with a diverse group of stakeholders, including patients, industry, FDA, and NCI, to raise awareness of, and to address, the critical need for advancing therapies for rare cancers and patient-focused drug development across all diseases.

Previous Work

Prior to re-joining Arent Fox, Deborah led the Food & Drug practice at a mid-sized law firm. She also previously served as Deputy General Counsel for Healthcare at BIO, the world ’s largest biotech trade association, and as lead US counsel to a global biotechnology company’s Global Regulatory Policy and Government Affairs teams.

Publications, Presentations & Recognitions

An industry leader in the development of the legislative biosimilar pathway and other federal laws and regulations, Deborah has published extensively, taught numerous courses, and participated in many conference panels on issues of interest to FDA-regulated industries.

Her publications include:

- Co-Author, “FDA Revises EUA for Respirators Manufactured in China ,” Arent Fox Alert, May 8, 2020
- Co-Author, “COVID-19: The Push for Serological Antibody Testing With a High Degree of Accuracy and Reliability,” Arent Fox Alert, May 7, 2020
- Co-Author, “Big Changes in FDA’s Serology/Antibody Testing Requirements ,” Arent Fox Alert, May 5, 2020
- Co-Author, “FDA Issues EUA for Face Masks ,” Arent Fox Alert, April 22, 2020
- Author, “FDA Issues Enforcement Policy for Telethermographic Systems During COVID-19 ,” Arent Fox Alert, April 20, 2020
- Co-Author, “Update: Importation and Distribution of Face Shields and Respirators During COVID-19 Pandemic,” Arent Fox Alert, April 6, 2020
- Author, “FDA Issues Enforcement Policy for Gowns, Other Apparel, and Gloves ,” Arent Fox Alert, March 30, 2020
- Author, “FDA Issues Enforcement Policy for Ventilators and Other Respirators ,” Arent Fox Alert, March 30, 2020
- Co-Author, “Update: Importation and Distribution of Face Masks and Respirators During the COVID-19 Pandemic,” Arent Fox Alert, March 27, 2020
- Author, “New FDA Enforcement Policy for Non-Invasive Remote Patient Monitoring Devices During the COVID-19 Pandemic ,” Arent Fox Alert, March 26, 2020
- Co-Author, “A New Marshall Plan: Congress Nears Passage of CARES Act ,” Arent Fox Alert, March 25, 2020
- Author, “Conduct of Clinical Trials of Medical Products During COVID-19 Pandemic: Guidance for Industry, Investigators, and Institutional Review Boards ,” Arent Fox Alert, March 25, 2020
- Co-Author, “The Importation of Personal Protective Equipment for Treatment of COVID-19 ,” Arent Fox Alert, March 24, 2020
- Co-Author, “Cannabis-Derived Botanical Drugs: A Viable Regulatory Pathway for Marketing Medical Edibles?,” *Food and Drug Law Journal*, Summer 2019 Issue
- Co-Author, “FDA Formally Announces Rulemaking to Amend Definition of Biological Product,” *The SciTech Lawyer*, Spring 2018 issue
- Co-Editor, 2018 FDLI Food and Drug Cosmetic Act Statutory Supplement
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Co-Author, “FDA Issues Much-Anticipated Draft Guidance on Interchangeable Biologics: Are the First Approvals on the Horizon?,” *ABA Health eSource*, March 2017

- Co-Author, “Shrinking Regulation in the New Administration,” *M&E Regulatory Alert*, February 2017

Deborah’s recent speaking engagements include:

- Curriculum Advisor, Introduction to Drug Law and Regulation, Food and Drug Law Institute; April 15-16, 2020
- Panelist, “Center for Drug Evaluation and Research Panel,” FDA Center Director Breakout Session, Food and Drug Law Institute; May 2, 2019
- Co-Presenter, “Corporate Structure, Intellectual Property & FDA Legal Considerations for Life Science Startups,” Medicine Innovation & Entrepreneurship Conference; April 27, 2019
- Presenter, “Regulation of Biological/Drug Development,” Food and Drug Law Institute Introduction to Biologics and Biosimilars Law and Regulation; October 3, 2018
- Presenter, “Tips and Strategies for Communicating with FDA,” American Conference Institute’s FDA Boot Camp; March 9, 2018

Professional Activities

Deborah is an active member of the American Bar Association (ABA). She is currently serving in numerous leadership roles within the ABA’s Science and Technology Law Section, including:

- Life Sciences Division Chair
- Program Chair
- Council Member
- Biotechnology, Healthcare Technology, and Medical Devices Co-Chair

Deborah also serves on the Appendix Cancer/Pseudomyxoma Peritonei Board of Directors, is a frequent contributor to the Food and Drug Law Institute, and is an engaged member of Women in Bio.

Life Beyond the Law

Deborah is a passionate patient advocate, working on behalf of patients with rare cancers and other diseases where there is current unmet medical need. In her leisure time, she enjoys spending time at the beach or on the water with her spouse and their two rescue dogs. Deborah also enjoys reading detective novels, espionage thrillers, historical fiction, and, because her spouse is an English Professor, annual nominees for literary awards.

Bar Admissions

District of Columbia

Maryland