SheppardMullin

Allison Fulton

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Allison Fulton is a partner in the Life Sciences team and is based in the firm's Washington, D.C. office. Allison advises biotech, pharmaceutical, medical device, food, dietary supplement and cosmetic companies in matters relating to the development, manufacture, and marketing of products regulated by the U.S. FDA.

Areas of Practice

Allison's areas of focus include assisting U.S. and international companies comply with premarket and postmarket FDA requirements, including product launch strategy, clinical trials, compliance with GxP (GMP, GLP, GCP), product promotion and labeling, recalls and other product safety issues. She regularly advises clients on acquisitions of life science companies and assets, and counsels clients on a variety of life science transactions, including clinical trial and investigator agreements, manufacturing, distribution and supply agreements, quality agreements, and various service agreements involving medical product technology and IP.

Allison also advises clients on COVID-19 matters such as emergency use authorizations (EUAs), laboratory issues including Clinical Laboratory Improvement Amendments (CLIA) and laboratory developed tests (LDTs), and state license requirements for the distribution of medical products. Allison regularly counsels companies on preparing for FDA inspections, responding to Form 483s and Warning Letters, remediating GMP and data integrity issues, and handling adverse events and medical device reports (MDRs).

Allison has a passion for novel technologies, and advises clients on product approval and clearance strategies for innovative products, including digital health technologies, precision medicine, and combination products. She has led numerous internal investigations involving allegations of product tampering, non-compliance with GMP, and off-label promotion. Allison acts as FDA counsel on civil litigation matters, such as false advertising and False Claims Act litigation.

Prior to her legal career, she worked as a software engineer where she specialized in software validation.

Allison earned her law degree from the University of Texas School of Law, where she was the managing editor of the Texas Intellectual Property Law Journal. She received her B.S. in Industrial Engineering from Northwestern University.

Allison devotes her pro bono practice to assisting veterans obtaining benefits for service-connected disabilities.

Honors

Shortlisted for Regulatory Attorney of the Year: FDA Pharmaceutical, *LMG Life Sciences,* 2021

Leading Life Sciences Lawyer - FDA Medical Device and FDA Pharmaceutical, *LMG Life Sciences*, 2021/2022

Best Lawyer in America, *Best Lawyers*, 2021-2022

"Life Sciences Star" – FDA Medical Device and FDA Pharmaceutical, *LMG Life Sciences*, 2018-2019

Articles

- Eye on Privacy 2021 Year in Review
  01.11.2022
- Upping Hospitals' Liability Defenses For COVID Measures
  Law360, 04.13.2020
- Marketing pet foods with CBD: A regulatory perspective
  PetfoodIndustry.com, 12.02.2019
- FDA In Review – Highlights for Food and Other FDA-Regulated Companies
  Association of National Advertisers, 11.2019
- Adapting To FDA's Proposal For Diagnosis Support Software
  Law360, 11.04.2019
- FDA warning letters shed light on enforcement priorities for CBD-infused food
  Food Dive, 10.17.2019
- Tips for When to Consider Legal Review of Quality System Investigations
  MD+DI, 09.05.2019
- How FDA considerations impact food and beverage acquisitions
  Food Dive, 08.15.2019
- Into the Weeds
  Walking the Regulatory Line of CBD in Cosmetics
  Cosmetics & Toiletries, 07.2019
- What We Learned From FDA's Public Hearing On Cannabis
  Law360, 06.04.2019
- "Submitting a new 510(k) for software changes: FDA guidance and an evolving pathway for digital health," *Digital Health Legal*, January 2018
- "FDA's Streamlined Requirements For Combination Products," *Law360*, January 2017
- "Additive manufacturing and 3D printing: US FDA's proposed draft guidance and industry perspectives," *Journal of Medical Device Regulation*, November 2016
- "5 Takeaways From FDA Medical Device Data System Guidance," *Law360*, August 2014
- "New Draft Guidance Would Clear Regulatory Hurdles for Developers," *BNA's Medical Devices Law & Industry Report*, July 2014

Privacy Law Blog Posts

- "FDA Joins Other Regulators in Focus on AI and Machine Learning," November 22, 2021

Cannabis Law Blog

- "DEA Deschedules Cannabinol-Containing Epidiolex," April 10, 2020

FDA Law Blog Posts

- "FDA White Paper Signals Shift to Performance-Based Reviews of Mature Quality Systems," May 19, 2022
- "FDA Releases Guidance for Digital Health Tech Used in Clinical Investigations," January 6, 2022
- "Breaking Down FDA's New Remote Monitoring Strategy," April 15, 2021
- "New State Genetic Privacy Law Directed at Consumer Genetic Tests," April 2, 2021
- "FDA Announces Facility Fees for OTC Drug Manufacturers," March 29, 2021
- "Recent FTC Settlement Serves as Reminder For Digital Health Developers," February 18, 2021
- "FDA Appointment Signals Increased Attention on Medical Device Cybersecurity," February 9, 2021
- "FDA's Action Plan for Artificial Intelligence: Highlights and Insights for Developers," January 12, 2021
- "FDA's Proposed Rule on "Intended Use" Confirms Agency Will Rely on "Any Relevant Source" of Evidence," October 1, 2020
- "FDA Update: The Latest on Vaccine Development, Inspections, and Conducting Clinical Trials During Covid-19," September 25, 2020
- "Latest Update on FDA's Software Pre-Cert Pilot Program," September 16, 2020
- "FDA Announces Plans to Resume Domestic On-site Inspections," July 13, 2020
- "FDA Issues Guidance on Manufacturing Drugs, APIs during COVID-19," June 22, 2020
- "Navigating FDA Policies for PPE, and Liability Protections," June 12, 2020
- "FDA Updates Policy to Curb Unreliable COVID-19 Antibody Tests," May 6, 2020
- "April 16 Update: Key FDA Actions for COVID-19 Devices and Therapies," April 16, 2020
- "Upping Hospitals' Liability Defenses For COVID Measures," April 14, 2020
- "Update: Key FDA Actions for COVID-19 Devices and Therapies," April 8, 2020
- "Personal Protective Equipment & Ventilators: How FDA Is Increasing Supply for the US Healthcare System," March 30, 2020
- "FDA Grants COVID-19 Diagnostic Emergency Use Authorizations, And Other Recent FDA Actions to Address COVID-19", March 16, 2020
- "FDA Postpones Ex-US Facility Inspections", March 11, 2020
- "How FDA is Reacting to the Coronavirus, and 2020 Regulatory Priorities", March 5, 2020
- "FDA Year in Review: A Shifting Regulatory Landscape," January 7, 2020

- "FDA Issues Warning Letters to 15 Companies, Consumer Update on CBD Safety," December 10, 2019
- "Adapting To FDA's Proposal For Diagnosis Support Software," November 8, 2019
- "New Set Of Guidance From FDA Provides Clarity On Digital Health Policies, Machine Learning," September 30, 2019
- "Tips for When to Consider Legal Review of Quality System Investigations," September 23, 2019
- "FDA's New Safety and Performance Based Pathway for Medical Devices Reflects a More Modern Approach to Finding Substantial Equivalence," September 20, 2019
- "Regulating E-Cigarettes Remains "Top Priority" For FDA," July 12, 2019
- "Medical Devices – Artificial Intelligence and Reactions to FDA's Proposed Oversight," June 25, 2019
- "Location Matters – Manufacturing Insights from FDA's Annual Report on Drug Quality," May 20, 2019
- "AAFCO Issues Updated Guidelines Regarding Hemp in Animal Food," May 8, 2019
- "FDA Update: Recent Trends and a New Regime," April 19, 2019

Healthcare Law Blog Posts

- "Digital Health in the Metaverse: Three Legal Considerations," May 31, 2022
- "Top 5 Legal Issues in Digital Health to Watch for in 2022," February 1, 2022
- "FDA Releases Guidances on Transition Plan for Devices Distributed Under Emergency Use Authorization (EUA) or Enforcement Policies During COVID-19," January 12, 2022
- "Going Virtual: Clinical Trials, Telemedicine, Electronic Medical Records, And All That." June 8, 2020
- "Key Health Care Provisions of the Coronavirus Aid, Relief, and Economic Security Act (the "CARES Act")," March 30, 2020
- "FDA Issues Warning Letter to Lab Marketing Three Laboratory-Developed Tests," April 22, 2019

Media Mentions

Sheppard Mullin Nabs FDA Pro From Sidley Austin
Law360, 01.23.2019

Speaking Engagements

Speaker, "Ensuring Regenerative Therapy Product Compliance with FDA," FDLI Regenerative Medicine: Regulatory, Legal, and Compliance Challenges for Cell and Gene Therapies Conference, June 8-9, 2021

Speaker, "Manufacturing and Quality System (QS) Regulation," FDLI Introduction to Medical Device Law and Regulation Conference, March 2-4, 2021

Speaker, "Innovative and Breakthrough Devices and Diagnostics and Evolving Regulatory Pathways," FDLI 2020 Annual Conference, October 6, 2020

Speaker, "Medical Device Manufacturing and The Quality System Regulation," FDLI Introduction to Medical Device Law and Regulation, April 8, 2020

Speaker, "The Long-Term Effects of COVID-19 on Life Sciences Companies," FDLI Law Over Lunch, April 22, 2020

Speaker, "Drug and Biologics Advertising and Promotion 101," The American Conference Institute (ACI) 36th Annual FDA Boot Camp, San Francisco, CA, June 24, 2020

Speaker, "Health Hazard Evaluations" and "Measuring the Effectiveness of Your Complaint Handling System," AdvaMed Medical Device Complaints, MDRs and Recalls Workshop, Washington, D.C., Feb. 11, 2020

Speaker, "Food and Drug Topics for Holiday Parties: News from 2019 and Predictions for 2020," FDLI Law Over Lunch, December 17, 2019

Events

The Biden Administration's FDA: What's Happened and What to Expect
Webinar, 09.02.2021

The Biden Administration's FDA: The First Six Months and What to Expect for the Rest of the Year
Webinar, 07.22.2021

FDLI Annual Conference: Exploring Advanced Topics in Food and Drug Law
05.07.2020

Life Sciences Roundtable: Critical Business Decisions During and After the COVID-19 Pandemic
Webinar, 04.28.2020

Cannabis Webinar Wednesday: Getting Your CBD/Hemp Product To Market- Current Issues in Risk Management
02.19.2020

Women in Healthcare Leadership Collaborative (WHLC) Presents: A View from the Capitol
2020 Healthcare Policy, Legal and Regulatory Predictions
Sheppard Mullin, New York and Sheppard Mullin, San Francisco, 01.23.2020

Healthcare - What You Need to Know in 2020
Roundtable and Networking Event
Sheppard Mullin, Washington D.C., 12.05.2019

Food Advertising, Labeling, and Litigation Conference: For the Food and Dietary Supplement Industries
Food and Drug Law Institute, 09.26.2019

Hemp-CBD: Enabling Growth by Managing Legal Risks
Celesq Webinar, 09.25.2019

Cannabis Webinar Wednesday: Hemp-CBD: Enabling Growth by Managing Legal Risks
07.17.2019

Podcasts & Webinars

Nota Bene Episode 71: Shifting Regulatory Landscapes at the FDA: Cannabis, Vaping and Intelligent Medical Devices with Allison Fulton
03.04.2020

Cannabis Webinar Wednesday: Getting Your CBD/Hemp Product To Market- Current Issues in Risk Management
02.19.2020

Cannabis Webinar Wednesday: Hemp-CBD: Enabling Growth by Managing Legal Risks
07.17.2019

Nota Bene Episode 32: A Snapshot of the FDA: Understanding the Basics of Regulations with Allison Fulton
04.17.2019

Practices

Digital Health

False Advertising, Lanham Act and Unfair Competition

FDA Regulatory

Intellectual Property

Industries

Food and Beverage

Life Sciences

Education

J.D., The University of Texas School of Law, 2005, *with honors*

B.A., Northwestern University, 1999

Admissions

District of Columbia