SheppardMullin

Audrey Mercer

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Audrey Mercer is an associate who specializes in the life sciences and healthcare industries and works out of the firm's Dallas office.

Areas of Practice

Audrey represents clients in the life sciences and healthcare industries by advising on regulatory compliance matters under federal and state law, with a primary focus on FDA legal, regulatory, and compliance matters. Audrey regularly counsels clients in the pharmaceutical and medical device industries on a wide range of regulatory and compliance matters relating to the development, manufacture, and marketing of FDA-regulated products – including, but not limited to: (i) product development through various FDA pathways, such as New Drug Applications, Accelerated Approval Applications, 510(k) Clearances, De Novo Classifications, and Premarket Approval Applications; (ii) labeling, advertising, and promotional review; (iii) drug price transparency reporting and related confidentiality issues; (iv) internal and external compliance investigations; (v) transparency reporting, (vi) product-related contracts, including, but not limited to, Clinical Trial Agreements, Quality Agreements, and Product Donation Agreements, (vii) due diligence for related corporate transactions; and (viii) compliance with other FDA post-market requirements, such as current good manufacturing practices (cGMP) and Quality System Regulation (QSR).

Additionally, Audrey has experience counseling clients on broader regulatory issues, such as healthcare facility licensing, state and federal fraud and abuse limitations, Medicare/Medicaid participation requirements, and conducting due diligence in transactional matters, among other regulatory topics.

Audrey is also a contributing member of Sheppard Mullin's Pro Bono Committee and regularly assists pro bono clients in completing United States Customs and Immigration Services applications.

Audrey earned her J.D. from Southern Methodist University Dedman School of Law in Dallas, Texas, where she graduated with honors. She was the recipient of the Don Smart Directed Research Award for her article titled, "A Renewed Emphasis on Charity Care: Incentivizing Nonprofit Hospitals to Address the Nation's Indigent Care Needs." Since joining the firm, Audrey has also been published in the New York Law Journal, Bloomberg Law, and Law360 for publications such as "Industry Fights Back Against Restrictions on Pharmaceutical Manufacturers' Ability To Offer Drug Cost-Sharing Subsidies," "New FDA Rules Can Weed Out Drugs Masquerading as Cosmetics," and "Rare FDA Move Shows Stance On Remote Monitoring Devices."

Honors

Healthcare Influencer, *GlobeSt's* Real Estate Forum, 2022

Articles

- What To Expect For Stem Cell Regulation Under Trump Admin
  Law360, 03.25.2025
- A Look At HHS' New Opinion On Patient Assistance Programs
  Law360, 02.18.2025
- 2025 Top-of-Mind Issues for Life Sciences Companies
  01.31.2025
- Takeaways From FDA's Updated Confirmatory Trial Guidance
  Law360, 01.23.2025
- The Future of FDA Policy: Reflections From the Summer of 'Chevron'
  New York Law Journal, 09.12.2024
- Are Concessions In FDA's Lab-Developed Tests Rule Enough?
  Law360, 05.08.2024
- FDA Warning Letter Tightens Reins On 'Research Only' Labels
  Law360, 04.22.2024
- 2024 Top-of-Mind Issues for Life Sciences Companies
  01.25.2024
- Tech Support: FDA's Evolving Regulatory Plan for Drug- and Device-Enabling Software
  Food and Drug Law Institute, 12.15.2023
- New FDA Rules Can Weed Out Drugs Masquerading as Cosmetics
  Bloomberg Law, 09.01.2023
- Rare FDA Move Shows Stance On Remote Monitoring Devices
  Law360, 06.23.2023
- 2023 Top-of-Mind Issues for Life Sciences Companies
  01.11.2023
- 6 Takeaways From LabSolutions 'Unnecessary Testing' Verdict
  Law360, 01.11.2023
- Industry Fights Back Against Restrictions on Pharmaceutical Manufacturers' Ability To Offer Drug Cost-Sharing Subsidies
  New York Law Journal, 01.09.2023
- Third Time's a Charm: The Supremes Will Finally Settle the Rule 9(b) False Claims Act Circuit Split
  Texas Lawyer, 07.08.2022

Healthcare Law Blog Posts

- "FDA Touts Continued Commitment to Cell and Gene Therapy Products through Trio of Guidances," October 6, 2025

- "CMS Promotes Competition, Transparency, Health Equity and More in the CY2025 Medicare Advantage and Part D Proposed Rule," November 13, 2023
- "The Drug Price Negotiation Program Faces Pushback from Private and Public Industry Participants," June 21, 2023
- "Payor-Led Initiatives to Strengthen Mental Health Resources," March 20, 2023
- "CMS Releases Guidance on Implementation of Rebate Programs for Certain Medicare Part B and Part D Drugs," February 22, 2023
- "Proposed Rule Leverages Section 1557 for Healthcare Equity," August 22, 2022
- "Supreme Court Discrimination Case Narrows Scope of Restitution for Individuals," May 25, 2022
- "Tax Break for Certain Medical Billing Services in Texas," March 1, 2022
- "Debate Continues Around Scope of Practice Expansion for APPs," December 13, 2021

FDA Law Blog Posts

- "What to Watch: Continued DTC Advertising Enforcement," December 2, 2025
- "What to Watch: Human Cell and Tissue Product Regulation," October 17, 2025
- "FDA Unleashes Wave of Enforcement: The Industry Faces a Crackdown on Drug Advertising," September 19, 2025
- "What to Watch: WHOOP Warning Letter," August 5, 2025
- "What's Going on with Human Cell and Tissue Products?," June 30, 2025
- "What to Watch: Potential Increase in Enforcement of 'RUO' Diagnostics," June 18, 2025
- "LDT Final Rule Series: Part 4 – Rule Overturned by Federal District Court," April 7, 2025
- "Finally, FDA's Final Word on Unapproved Use Communications," February 7, 2025
- "FDA Dumps Trio of Device-Related Guidances Prior to Administration Change," January 27, 2025
- "FDA Furthers Efforts to Improve the Accelerated Approval Pathway through New Draft Guidance on Confirmatory Trials," January 14, 2025
- "New Accelerated Approval Guidance Underscores Need for Accountability," December 19, 2024
- "LDT Final Rule Series: Part 3 – Legal Challenges," December 16, 2024
- "FDA Releases Long-Anticipated Guidance on Predetermined Change Control Plans for Devices That Utilize AI/ML Software," December 5, 2024
- "LDT Final Rule Series: Part 2 – Response to the Rule," June 6, 2024
- "LDT Final Rule Series: Part 1 – Rule Overview," April 30, 2024
- "FDA Warning Letter Regulates 'Research Only' Labels," April 24, 2024

- "Oregon Prescription Drug Price Transparency Act in Limbo," March 8, 2024
- "OIG Permits Medical Device Manufacturer's Cost-Sharing Subsidies for Medicare Beneficiaries in Clinical Trial," January 30, 2024
- "2024 Top-of-Mind Issues for Life Sciences Companies," January 25, 2024
- "FDA's Proposed Rule on LDT Regulation and the Debate over Agency Deference," October 18, 2023
- "FDA Clarifies Labeling Expectations for Prescription Drug Use-Related Software," September 26, 2023
- "FDA Maintains Focus on "Intended Use" for Software-Enabled Medical Devices," July 26, 2023
- "FDA Clarifies Approach to Pediatric Drug Development," June 5, 2023
- "Withdrawal of Drug Approval Highlights Risk of Accelerated Approval Pathway," April 26, 2023
- "FDA To Require Demonstration of Cybersecurity Safeguards for Pre-Market Submissions of Certain Medical Devices," April 10, 2023
- "FDA Expands Inspection Guidance to Apply to Device Manufacturers," December 27, 2022
- "FDA Lightens Promotional Restrictions for Certain COVID-19 Drugs with Emergency Use Authorization," November 30, 2022
- "OIG Limits Pharmaceutical Manufacturers' Ability to Offer Drug Cost-Sharing Subsidies," October 13, 2022
- "FDA Delays Enforcement of UDI Reporting Requirements for Consumer Health Products," August 8, 2022
- "FDA Issues Final Guidance on Drug and Biological Instructions for Use (IFU)," July 21, 2022

Events

2024 FDLI Annual Conference
Washington, DC, May 15-16, 2024

2023 FDLI Annual Conference
May 17-18, 2023

WHLC Dobbs Series
Fireside Chat: The Effect of Dobbs on Health Equity
Webinar, 11.09.2022

Practices

Governmental

FDA Regulatory

Healthcare

Women in Healthcare Leadership Collaborative

Industries

Healthcare

Life Sciences

Education

J.D., Southern Methodist University Dedman School of Law, 2021

B.S., University of Texas at Austin, 2013

Admissions

Texas

New York