SheppardMullin

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Dominick DiSabatino is a partner on the Life Sciences team in the firm's Washington, D.C. office.

Areas of Practice

Dominick's practice focuses on complex FDA and healthcare regulatory, compliance and legal matters in the life sciences industry. Drawing from in-house secondments with clients of various growth stages, Dominick counsels pharmaceutical, biotechnology, cosmetics and medical device companies on critical business decisions spanning the entire product life cycle, from research and development to product launch and commercialization.

Dominick offers clients a deep knowledge of advertising and promotion of FDA-regulated products, organizational OIG compliance programs, labeling review and approval strategies, managed markets and payer interactions and privacy/data security concerns. He also advises his clients on matters regarding commercial contracting and supply chain logistics, clinical trial agreements, federal transparency obligations and interactions with FDA such as post-market adverse event and product complaint reporting, facility inspections and Form 483s. With his background in intellectual property law, Dominick identifies client issues related to patents, trademarks, copyrights and trade secrets.

Dominick is committed to pro bono service. He has counseled nonprofit organizations focused on health care integration and optimization and post-incarceration reentry programs. He also represented New York City's senior citizens in housing disputes and provided free speech advice for press operations in Africa.

Honors

Top Author, *JD Supra* Readers' Choice Awards, 2024

Rising Star, FDA: Pharmaceutical, *LMG Life Sciences*, 2023

"Ones to Watch," *Best Lawyers*, 2024

Articles

- 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
- HHS Advisory Opinion Serves As Free Drug Program Guide
  Law360, 03.20.2023
- 2023 Top-of-Mind Issues for Life Sciences Companies
  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
- HHS' Free Genetic Testing Opinion Raises Questions For Cos.
  Law360, 06.03.2022
- OIG Advisory: Yet Another Favorable Decision for Medical Device Manufacturers
  New York Law Journal, 03.23.2022
- AbbVie Calif. Settlement Guides Nurse Education Compliance
  Law360, 08.13.2020
- Cosmetics Companies Using Instagram Face Regulatory Risk
  Law360, 03.07.2018

FDA Law Blog

- "FDA Makes Good on Its Promise to Regulate Laboratory-Developed Tests," April 30, 2024
- "FDA Warning Letter Regulates 'Research Only' Labels," April 24, 2024
- "Time to Refresh? FDA Issues Draft Guidance on Key Information and Informed Consent," March 19, 2024
- "Oregon Prescription Drug Price Transparency Act in Limbo," March 8, 2024
- "FDA's Office of Prescription Drug Promotion Issues Its First Untitled Letter of the Year to Novartis for Misleading Statement Relating to KISQALI®," February 2, 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 Issues Final Rule and Guidance on Direct-To-Consumer Prescription Drug Advertisements," January 18, 2024
- "From Good Reprint Practices to SIUU Communications: What Firms Need to Know," November 10, 2023

- "OIG General Compliance Program Guidance November 2023," November 8, 2023
- "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
- "Context is Key: FDA Sends a Strong Message About Efficacy Claims," September 7, 2023
- "FDA's Office of Prescription Drug Promotion Issues Second Untitled Letter of the Year to Exeltis for Misleading Statements Relating to SLYND®," August 25, 2023
- "FDA Approves First Over-the-Counter Daily Oral Contraceptive," August 3, 2023
- "FDA Maintains Focus on "Intended Use" for Software-Enabled Medical Devices," July 26, 2023
- "FDA Issues First Untitled Letter of the Year to Xeris Pharmaceuticals," June 15, 2023
- "DOJ Continues to Discuss Updates to Compliance Program Guidance and Corporate Enforcement Policies," June 15, 2023
- "FDA Issues Proposed Rule for Standardized and Accessible Patient Medication Information," June 13, 2023
- "FDA Clarifies Approach to Pediatric Drug Development," June 5, 2023
- "FDA Cracking Down on Unapproved HCT/Ps with Fourth Untitled Letter of 2023," June 2, 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 Issues First Untitled Letter of the Year to HCT/P Manufacturer," March 29, 2023
- "OIG Advisory Opinion Alert: Medical Flights for Patient Access," March 7, 2023
- "FDA Issues Warning Letter to RightEye, LLC For Misbranding and Adulteration," February 13, 2023
- "FDA Lightens Promotional Restrictions for Certain COVID-19 Drugs with Emergency Use Authorization," November 30, 2022
- "Pharmaceutical Manufacturers Ask EDVa to Allow Cost-Sharing Under the AKS," November 21, 2022
- "OIG Limits Pharmaceutical Manufacturers' Ability to Offer Drug Cost-Sharing Subsidies," October 13, 2022
- "Biogen Settlement Summary," October 6, 2022
- "Charging for Investigational Drugs Under an IND Questions and Answers, Draft Guidance for Industry, August 2022," August 31, 2022
- "FDA Issues Final Guidance on Drug and Biological Instructions for Use (IFU)," July 21, 2022
- "FDA Issues Untitled Letter to Althera Pharmaceuticals for Statements Relating to ROSZET®," June 23, 2022
- "FDA Issues Untitled Letter to Bausch Health Companies for Misleading Statements Relating to DUOBRII™," April 19, 2022
- "OIG Advisory Opinion Alert: Yet Another Favorable Decision for Medical Device Manufacturers," March 17, 2022
- "FDA Issues Untitled Letter to Althera Pharmaceuticals for Statements Relating to ROSZET®," June 23, 2022

Healthcare Law Blog Posts

- "Connecticut Follows in the Footsteps of Other Jurisdictions Requiring Registration of Pharmaceutical Representatives," October 25, 2023
- "CMS Releases Guidance on Implementation of Rebate Programs for Certain Medicare Part B and Part D Drugs," February 22, 2023

Speaking Engagements

Speaker, "Pharmaceutical Compliance Congress 2023," April 25 - 27, 2023

Events

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

Pharmaceutical Compliance Congress 2024
April 16-18, 2024

Advertising & Promotion for Medical Products Conference
Promotional Challenges and Considerations for Rare Disease Treatments
11.03.2023

Compliance Congress for Specialty Products Conference
Boston Convention & Exhibition Center (BCEC), Boston, MA, September 19-21, 2023

2023 FDLI Annual Conference
May 17-18, 2023

Practices

FDA Regulatory

Governmental Practice

Intellectual Property

Industries

Life Sciences

Education

J.D., George Washington University Law School, 2012, *with honors*

B.S., Bucknell University, 2008

Admissions

District of Columbia

New York

United States Patent and Trademark Office