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Dominick P. DiSabatino

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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, 2024-2025

Rising Star, FDA: Pharmaceutical, *LMG Life Sciences*, 2023-2025

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

Articles

- Key Trends For Life Sciences Cos. To Watch In 2026
  Law360, 01.08.2026
- Texas Suit Marks Renewed Focus on Service Kickback Theory
  Law360, 09.26.2025

- 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
- Key Takeaways From FDA's Latest Social Media Warnings
  Law360, 12.03.2024
- Proposed Legislation May Crack Down On Online Drug Ads
  Law360, 09.25.2024
- The Future of FDA Policy: Reflections From the Summer of 'Chevron'
  New York Law Journal, 09.12.2024
- FDA Warning Indicates Scrutiny Of Regenerative Health Cos.
  Law360, 06.06.2024
- 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
- 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

- "What to Watch: Continued DTC Advertising Enforcement," December 2, 2025
- "Congress Joins the Biomanufacturing Onshoring Party," November 20, 2025
- "Texas Sues Johnson & Johnson and Kenvue Over Tylenol: Scientific Evidence, Regulatory Shifts, and the Future of OTC Drug Labeling," November 4, 2025
- "What to Watch: Human Cell and Tissue Product Regulation," October 17, 2025
- "FDA Touts Continued Commitment to Cell and Gene Therapy Products through Trio of Guidances," October 6, 2025
- "FDA's Wave of Untitled Letters Signals Stricter Scrutiny for DTC Pharma Ads," October 1, 2025
- "FDA Unleashes Wave of Enforcement: The Industry Faces a Crackdown on Drug Advertising," September 19, 2025
- "FDA's Vast Ad/Promo Warning – Enforcement Ramp-Up or PR Nothingburger?," September 10, 2025
- "What to Watch: WHOOP Warning Letter," August 5, 2025
- "DOJ False Claims 'Working Group' Update," July 28, 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
- "FDA Ratchets Enforcement on Social Media Promotion in New Warning Letter," June 11, 2025
- "Reflections on the FDLI 2025 Annual Conference – Differing Tones, Shared Goals," May 16, 2025
- "Onshoring Pharma Ops: Reading Recent EO and Policy Tea Leaves," May 9, 2025
- "LDT Final Rule Series: Part 4 – Rule Overturned by Federal District Court," April 7, 2025
- "Reminder: FDA Does, In Fact, Review DOF," March 11, 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
- "Key Takeaways from FDA's Latest Social Media Warnings," December 5, 2024

- "DOJ Updates Guidance on Evaluation of Corporate Compliance Programs," October 29, 2024
- "Ubrelvy Untitled Letter – A Double Fault for AbbVie? Or Makeup Misread for FDA?," September 17, 2024
- "Krazati Untitled Letter: A Cautionary Tale for CFL Promotion of Accelerated Approval Drugs," August 14, 2024
- "FDA's Second Untitled Letter of the Year – An Apparently Tough Choice Between Raising Awareness and Public Safety for Anaphylaxis Drugs," July 30, 2024
- "FDA Revisits and Updates Guidance on Addressing Misinformation – Ten Years Later," July 16, 2024
- "LDT Final Rule Series: Part 2 – Response to the Rule," June 6, 2024
- "FDA Gets Technical on HCT/P Rules in Warning Letter to Human Tissue Company," May 31, 2024
- "OIG Issues Favorable Advisory Opinion Regarding Patient Assistance Funds," May 8, 2024
- "LDT Final Rule Series: Part 1 – Rule Overview," 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

Media Mentions

Blip Or Trend? FDA Guidance Fell Off Steeply In 2025
Law360, 01.13.2026

FDA To Ease Regulation Of Wearables, Decision Software
Law360, 01.06.2026

Congress Introduces Bill to Create National Biomanufacturing Center of Excellence
pharma manufacturing, 11.25.2025

FDA Offers Up New Pathway for Drugs That Can't Clear Normal Approval Hurdles
Law.com, 11.21.2025

Tylenol Autism Warning May Face Legal, Free Speech Hurdles
Law360, 10.28.2025

FDA Proposes Neurological Risk Label for Acetaminophen
Packaging Digest, 10.06.2025

Trump Tylenol Warning Kicks Off Label Change Drugmaker May Fight
Bloomberg Law, 09.26.2025

Speaking Engagements

Speaker, "Introduction to Advertising and Promotion for Medical Products," Food & Drug Law Institute, October 16, 2024

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

Events

26th Annual Pharmaceutical and Medical Device Ethics and Compliance Congress
Navigating Regulatory Uncertainties in Life Sciences
Grand Hyatt Washington, Washington, DC, 10.22.2025

Introduction to Advertising and Promotion for Medical Products 2025
Core Fundamentals
10.16.2025

2025 iC³ Life Science & Healthcare Innovation Summit
Putting Patients First: Access & Business Strategies for Better Care
2201 N Stemmons Freeway, Dallas, TX 75207, 09.16.2025

2025 FDLI Annual Conference
Washington, DC, May 15-16, 2025

Pharmaceutical Compliance Congress 2025
McLean, VA, April 28-30, 2025

Introduction to Advertising and Promotion for Medical Products
Core Fundamentals
10.16.2024

5th Annual Promotional Review Summit
Fireside Chat: CFL Guidelines
09.26.2024

Compliance Congress for Specialty Products Conference
Pre-Launch Compliance Considerations for Specialty Pharmaceuticals
09.25.2024

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

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