Kyle A. Dolinsky
Partner

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Kyle provides business-minded advice and resolves disputes for companies in the life sciences and health care sectors. His clear-cut, practical guidance help clients achieve their objectives in an ambiguous regulatory landscape.

OVERVIEW

Kyle advises companies in the life sciences and health care sectors on a range of key regulatory, litigation, government enforcement, and transactional matters. His diverse practice encompasses issues related to FDA-regulated products, health care fraud and abuse, product liability actions, and supply chain, among other areas.

Kyle's proactive approach to regulatory matters helps clients mitigate potential risk throughout the product lifecycle. He provides analysis, advice, and transactional support on FDA regulatory issues related to a wide range of products, including prescription and OTC drugs, food, medical devices, biologics, and compounded products. Kyle handles all aspects of his client's FDA compliance, offering particularly deep experience in labeling, promotion, and cGMP matters. He also negotiates agreements for companies across the supply chain of FDA-regulated products. Kyle's regulatory experience extends to the health care sector, where he advises clients across complex issues involving the Anti-Kickback Statute, Stark Law, Physician Payment Sunshine Act, and False Claims Act.

Kyle brings a comprehensive understanding of regulatory schemes to his work defending pharmaceutical, medical device, and health care industry clients in litigation and investigations. He handles cases involving consumer and third party payor class actions, contract disputes, the False Claims Act, the Foreign Corrupt Practices Act, and products liability. Kyle's experiences both in and out of the courtroom inform a holistic perspective and approach.

Kyle maintains an active pro bono practice. His work includes trying a prisoner's civil rights case to settlement before the U.S. District Court for the District of New Jersey, and serving as co-counsel with the American Civil Liberties Union of Delaware (ACLU) and Community Legal Aid Society, Inc. (CLASI) in representing mentally ill inmates being held in solitary confinement by the Delaware Department of Correction. Kyle has also represented homeowners in tangled title and fraudulent conveyance cases.

** Admitted in Pennsylvania and New Jersey; application pending for admission in California.*

REPRESENTATIVE MATTERS

- Represented a clinical laboratory in a CMS investigation and administrative procedures relating to billing practices.
- Advised an OTC drug manufacturer on labeling and promotional issues for products without a final, published OTC monograph.
- Provided analysis and advice to a pharmaceutical manufacturer hoping to engage in certain multimedia disease awareness communications with health care providers.
- Represented a CLIA-certified clinical laboratory in resolving third-party subpoenas related to the use of their testing in litigation.
- Represented clients in consumer class actions through the motion to dismiss, discovery, expert, and summary judgment phases of litigation.
- Advised a food manufacturer client on labeling issues and package design for products entering the U.S. market for the first time.
- Assisted a biologic product manufacturer with FDA regulatory-related sections of filings with the SEC.
- Analyzed FDA Forms 483, 510(k) clearances, and medical device reports, among other documents, in regulatory due diligence to support a merger deal.
- Provided FDA and USDA regulatory diligence in a client's acquisition of a food processor.
- Analyzed documents, interviewed employees, and drafted investigation memo to pharmaceutical manufacturer client in internal investigation of potential False Claims Act claims.
- Advised a retailer of OTC drug products on expiration date regulations in connection with government investigations.
- Advised a clinical laboratory client in building its compliance program, with an eye toward health care fraud and abuse issues.
- Defended a law firm client in a putative class action arising from a professional liability issue, including discovery, class certification analysis, damages analysis, engaging with expert witnesses, and settlement negotiations.
- Defended pharmaceutical companies against products liability actions for personal injury and consumer protection and third-party payor class actions in jurisdictions across the U.S.
- Conducted company interviews to support a client's preparations for meetings with a corporate monitor pursuant to a Delayed Prosecution Agreement arising from alleged violations of the Foreign Corrupt Practices Act.

AWARDS

- *Best Lawyers in America®: Ones to Watch:* Life Sciences Practice (2024-2025)
- Washington and Lee Law Counsel Law Review Award for Best Note, "CAD's Cradle: Untangling Copyrightability, Derivative Works, and Fair Use in 3D Printing"

TOP AREAS OF FOCUS

- FDA Regulatory + Risk Management Counseling
- Health Care + Life Sciences
- Pharmaceutical + Medical Device Litigation + Counseling

ALL AREAS OF FOCUS

- FDA Regulatory + Risk Management Counseling
- Fraud + Abuse Litigation + Investigations

- Health Care + Life Sciences
- Health Care Litigation
- Litigation + Trial
- Pharmaceutical + Medical Device Litigation + Counseling
- Product Liability

EDUCATION AND CERTIFICATIONS

EDUCATION

- Washington and Lee University School of Law, J.D., *summa cum laude*, 2014, managing editor, *Washington and Lee Law Review*
- Hamilton College, B.A., *magna cum laude*, 2009, philosophy and creative writing

BAR ADMISSIONS

- Pennsylvania
- New Jersey

COURT ADMISSIONS

- U.S. Court of Appeals, Third Circuit (2015)
- U.S. District Court, Eastern District of Pennsylvania (2015)
- U.S. District Court, District of New Jersey

SPEAKING ENGAGEMENTS

- Speaker, "Increasing Diversity in Clinical Trials: FDA Guidance and Industry Efforts," Medmarc Webinar, October 26, 2022.

PUBLICATIONS

- Co-author, "A Model's Credibility Is in the Details: FDA Draft Guidance on the Use of AI Models in Drug and Biological Product Development," *Troutman Pepper Locke*, February 12, 2025.
- Podcast, "AI and Pharmacovigilance Under the FDA's New Emerging Drug Safety Technology Program," *The Good Bot: Artificial Intelligence, Health Care, and the Law*, December 11, 2024.
- Co-author, "Updated FDA Draft Guidance Instructs Sponsors on Content, Format, Timing, and Procedures for Submitting Diversity Action Plans for Clinical Studies," *Troutman Pepper*, July 9, 2024.
- Podcast, "The FDA's Response to AI Medical Innovation," *The Good Bot: Artificial Intelligence, Health Care, and the Law*, June 25, 2024.
- Co-author, "FDA Issues Final Rule on Regulation of Laboratory Developed Tests," *Troutman Pepper*, May 23, 2024.
- Co-author, "New FDA Guidance on AI and Medical Products," *Troutman Pepper*, April 10, 2024.
- Co-author, "FDA Proposes New Rules for Prescription Drug Labeling," *Troutman Pepper*, June 5, 2023.
- Co-author, "FDA Draft Guidance Instructs Sponsors on Content and Timing of Diversity Plans for Clinical Trials ," *Troutman Pepper*, June 14, 2022.

MEDIA COMMENTARY

- Quoted, "FDA's New Guidance Plan to Face Trump's Transparency Efforts," *Bloomberg Law*, December 27, 2024.