FOLEY & LARDNER LLP

Kyle Y. Faget

Partner

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Kyle Faget is a Boston-based partner and a health care and life sciences lawyer with Foley & Lardner LLP. Kyle is the Co-Chair of the firm's Health Care Practice Group, and Co-Chair of the Health Care & Life Sciences Sector's Medical Device and Equipment Area of Focus. Kyle advises investors, academic medical centers, physician practices, and consultants on a range of business, legal and regulatory issues affecting the telemedicine industry. She helps companies build and refine corporate compliance programs, including advising clients on regulatory and compliance matters involving the Food, Drug and Cosmetic Act (FDCA), the False Claims Act (FCA), the Anti-Kickback Statute (AKS), the AdvaMed Code and the PhRMA Code. She regularly drafts and negotiates agreements required for the development and commercialization of pharmaceutical and medical device products, including licensing agreements, collaboration agreements, clinical trial agreements, and an array of services agreements. Prior to joining the firm, Kyle held in-house positions at pre-commercial and commercial stage companies.

Telemedicine, Telehealth, and Digital Health

"Foley is the premier firm for telehealth counsel."
"A market leader in telemedicine issues." "This is the Dream Team."
– Chambers USA: America's Leading Business Lawyers (2020, 2021, 2022)

Kyle was recognized by *Chambers USA: America's Leading Lawyers for Business* for her work in the practice area of Healthcare in 2022.

Kyle works with start-up and established entrepreneurs to create direct-to-consumer medical services using synchronous and asynchronous telemedicine offerings. She advises on strategic models for care delivery and revenue streams, state-by-state telemedicine modalities and practice standards, contracting with laboratories and pharmacies, and e-commerce issues. Kyle also assists digital health innovators understand and navigate the FDA regulatory landscape.

Kyle has married her years of experience counseling pharmaceutical and medical device companies on their brick-and-mortar clinical trial programs with her telehealth practice to offer cutting-edge decentralized clinical trial advice.

Clinical Research, Clinical Trials and Life Sciences

Kyle has extensive experience drafting and negotiating agreements with and for contract research organizations and site management organizations. She regularly drafts and negotiates clinical trial agreements, informed consents and other clinical development agreements on behalf of institutions and pharmaceutical and medical device clients. Kyle also advises clients on how to leverage and operationalize decentralized clinical trials.

Kyle has also drafted and negotiated a broad swath of operational agreements for her pharmaceutical and medical device clients, including manufacturing agreements, distribution agreements, master services agreements and material transfer agreements.

“Kyle is at the top of our collective list for quality of advice, depth of understanding and knowledge of the industry, responsiveness, and just plain reliability.”
– *Chambers USA: America’s Leading Business Lawyers (2020, 2021)*

FDA Regulatory

Kyle regularly advises telehealth, pharmaceutical and medical device clients regarding advertising and promotion issues, including off-label promotion. She regularly assesses marketing materials directed toward health care providers and direct-to-consumer advertising campaigns for compliance with the Food, Drug and Cosmetic Act and FDA Guidance documents. Kyle also helps digital health clients navigate the FDA regulatory process when developing new digital health products.

Corporate Compliance

Kyle has assisted multiple pharmaceutical and medical device clients build and operationalize corporate compliance programs. She has also advised clients on compliance with Corporate Integrity Agreements (CIAs). Her work has included drafting compliance policies and regularly conducting sales force training. Kyle has also assisted a number of life sciences companies enter the U.S. market compliantly.

Awards and Recognition

Kyle was selected by her peers for inclusion in *The Best Lawyers in America*® in the field of Biotechnology and Life Sciences Practice as well as Health Care Law (2023-2024). She was listed in *Chambers USA: America’s Leading Lawyers for Business* for her work in the practice area of Healthcare in 2021, 2023, and 2024. She was elected to the Massachusetts Super Lawyers® rising stars in 2018 – 2019, an honor received by only 5% of Massachusetts attorneys. Kyle was also recognized by the *JD Supra* Readers’ Choice Awards, Top Author – Life Sciences, 2024. Prior to joining Foley, Kyle was a Microsoft fellow at University of Michigan Law School where her research focused on FDA regulations.

Affiliations

Kyle is a member of the American Health Lawyers Association, and her pro bono work includes advising telemedicine clients regarding state laws impacting physician practices. In 2023, Kyle was selected as Fellow by the American Bar Foundation (ABF). Membership is limited to just 1% of lawyers licensed to practice in each jurisdiction. Members are nominated by their peers and selected by the ABF Board. Kyle is the former chair of the board of directors of Fenway Health, a Federally Qualified Community Health Center.

Community Involvement

She currently serves as a Practical Guidance Life Sciences advisory board member for LexisNexis. She previously served on the board of directors for Fenway Health as well as GLAD Legal Advocates and Defenders.

Presentations and Publications

- Speaker, “Apply Key Lessons from Decentralized and Remote Clinical Trials,“ 5th Clinical Trial Agreements (August 21, 2024)
- Co-author, “LDTs: FDA Rolls Out a Phased Implementation for New Regulatory Requirements,” *Health Care Law Today* (May 20, 2024)
- Co-author, “New Favorable OIG Advisory Opinion Allows Patient Assistant Programs Funded by Drug Manufacturers,” *Health Care Law Today* (April 25, 2024)
- Co-author, “FDA Continues to Take Stance That it Will Not Issue CBD Rules,” *Health Care Law Today* (April 24, 2024)
- Co-author, “FDA: New Guidance for Non-interventional Studies of Drug Safety and Effectiveness,” *Health Care Law Today* (April 1, 2024)
- Speaker, “Balancing Innovation and Safety: AI in Health Care,“ Northwest Regional Telehealth Resource Center Telehealth Conference (April 30, 2024)
- Speaker, “Advancing Health Care Access: Integrating Telemedicine Policy, Research and Pharmacy Services,“ Northwest Regional Telehealth Resource Center Telehealth Conference (April 29, 2024)
- Co-author, “Clinical Research: FDA Issues Draft Guidance on Informed Consent,” *Health Care Law Today* (March 14, 2024)
- Co-author, “Clinical Trials: FDA Issues Finalized Charging Guidance for Investigational Drug Use,” *Health Care Law Today* (March 13, 2024)
- Co-author, “OIG Opines on Subsidizing Medicare Cost-Sharing for Clinical Trials,” *Health Care Law Today* (February 26, 2024)
- Speaker, “Review CTAs in the Context of Decentralized Trials and Remote Monitoring,” Clinical Trial Agreement Forum (August 29, 2023)
- Speaker, “Examine Biological Samples Clauses in ICFs and Clinical Trial Agreements,” Clinical Trial Agreement Forum (August 29, 2023)
- Speaker, “Getting Rid of the Stupid Stuff – Fostering a Culture of Continuous Improvement,” HealthIMPACT Forum (June 7, 2023)

- Speaker, “How Decentralized Clinical Trials Are Changing the Landscape and What You Need to Know,” Berkley Life Sciences Webinar (May 15, 2023)
- Speaker, “Recent Challenges to the Compliance and Internal Audit Officer,” 2022 Compliance & Internal Audit Conference (November 30, 2022)
- Speaker, “Federal Anti-Kickback Statute: Protecting Federal Healthcare Programs, Scope and Elements of the Law, Statutory Exceptions, and Other Laws Implicated,” Lexis Nexis 4-Part Video Series
- Speaker, “Political Determinants of Health,” CNFL HIMSS Webinar (June 2, 2021)
- Speaker, “Negotiate for the Use of Biospecimens Outside of the Trial,” Clinical Trial Agreements Conference (January 25, 2021)
- Speaker, “Telemedicine’s New Frontier: Direct-to-Consumer Medicine,” ACC’s Virtual Annual Meeting (October 12-16, 2020)
- Speaker, “Regulation of Digital Health During and After COVID-19,” Food Drug Law Institutes, Digital Health Technology and Regulation During COVID-19 and Beyond (September 10, 2020)
- Speaker, “Federal Sunshine Act Changes and State Reporting Requirements,” ACC Webcast (August 26, 2020)
- Speaker, “Guidance for Deciding Whether to Reopen and Legal Implications of Reopening,” American Bar Association Health Law Webinar (May 22, 2020)
- Speaker, “Navigating the Legal and Regulatory Considerations of a Decentralized Trial,” 2nd Annual Virtual Clinical Trials (May 19-20, 2020)
- Speaker, “The New Drug Approval Process: NDA Submission and Review,” Food Drug Law Institute’s Introduction to Drug Law and Regulation (April 15-16, 2020)
- Speaker, Business of Personalized Medicine Summit 2020 (February 27, 2020)
- Speaker, “Bringing 2020 Focus to Telemedicine Reimbursement,” TeleSpecialists Webin (February 5, 2020)
- Speaker, “Legal Update: Hot Topics in Long Term Care,” New England Alliance Annual Meeting (January 15-17, 2020)
- Speaker, “Telemedicine and Medical Devices: What You Need to Know,” MedTech Impact Expo & Conference (December 13-15, 2019)
- Speaker, “Walking the Fine Line: Compliant Patient Advocacy and HCP Engagement Strategies,” 5th Bio/Pharmaceutical Product Launch Summit (October 28-29, 2019)
- Speaker, “Ensuring Regulatory Alignment with Innovative Virtual Siteless Clinical Design Trial Methodologies and wearables to Support Drug Development,” RAPS Regulatory Convergence Conference (September 24, 2019)
- Speaker, “TeleHealth and Compliance Challenges,” HCCA’s Boston Regional Conference (September 6, 2019)
- Speaker, “Making Telehealth an Essential Component to Care Delivery for Older Adults,” American Telemedicine Association 2019 Annual Conference & Expo (April 14-16, 2019)
- Speaker, “What is Happening in Telehealth Policy?” NatCon19’s TLunch 10 (March 26, 2019)

- Speaker, “Telemedicine and Direct to Consumer Medical Devices,” 10th Annual Global Partnership for Telehealth Conference (March 20-22, 2019)
- Speaker, “Legal Considerations in First Time CRO Contracts – Pitfalls, Risks and Protections,” CRO Partnership & Oversight Excellence (March 7, 2019)
- Speaker, “Digital Health and the FDA: Top 5 Legal Issues to Understand,” American Telemedicine Association (February 13, 2019)
- Speaker, “Up and Coming Technology,” Telehealth Technology Summit, New Orleans, Louisiana (December 13, 2018)
- Speaker, “Legal Issues in Telehealth Technology,” Telehealth Technology Summit, New Orleans, Louisiana (December 12, 2018)
- Speaker, “Telemedicine & Medical Devices: Legal and Regulatory Issues: Tech Vendor Key Issues, FDA Device Regulation and Certification, FDA Software as a Medical Device Regulation vs Clinical Decision Support Rules,” 5th Annual Florida TeleHealth Summit, St. Petersburg Beach, Florida (November 8, 2018)
- Speaker, “Telemedicine Regulations AHLA Distance Learning” (October 17, 2018)
- Panelist, “Telehealth Panel: Treating Patients Beyond the Physician’s Office,” WEDI’s 2018 National Conference, Washington, D.C. (October 15, 2018)
- Speaker, “Direct-to-Patient Telemedicine Legal and Regulatory Considerations,” Northwest Regional Telemedicine Center, Salt Lake City, Utah (October 2, 2018)
- Speaker, “Telemedicine & Medical Devices: Legal and Regulatory Issues,” 7th Annual Alabama Telehealth Summit (August 14, 2018)
- Speaker, “Behavioral Health in a Digital World, Trends and Considerations,” Boston Health IT Summit, Boston, Massachusetts (August 8, 2018)
- Speaker, “Behavioral Health in a Digital World: Trends and Considerations,” Boston Health IT Summit, Boston, Massachusetts (August 7, 2018)
- Speaker, “The New Drug Approval Process, as part of FDLI’s Introduction to U.S. Drug Law and Regulation,” San Francisco, California (July 24, 2018)
- “FDA Regulatory Update: 510(k) Guidance, ACC Quick Hits” (May 1, 2018)
- Speaker, “The New GDPR Regulations: What Clinical Operations Needs to Know,” NE Clinical Operations Executive Breakfast, Cambridge, Massachusetts (April 24,2018)
- Speaker, “Reading the Tea Leaves: Recent Trends in Regulatory Enforcement of New England ALFs,” New England Regional Winter Conference and Annual Meeting, Woodstock, Vermont (January 10, 2018)
- Speaker, “FMV for Clinical Trial Best Practices,” Clinical Trial Legal and Contracting Forum, Philadelphia, Pennsylvania (December 4, 2017)
- Panelist, “Monitoring Non-Promotional Activities within a Complex Global Organization,” CBI Compliance Congress on Non-Promotional Activities, Philadelphia, Pennsylvania (July 2017)
- Speaker & Panelist, “Gain an Understanding of the Importance of FMV in Clinical Trials” & “Best Practices for Open Payments Reporting of HCP Spend,” CBI 4th Annual FMV Congress, Philadelphia, Pennsylvania (March 2017)

- Panelist, “A Conversation About Diversity and Inclusion: The Questions You Wanted to Ask,” Women in Law Empowerment Forum, Boston, Massachusetts (November 2016)
- Panelist, “Maintaining Effective Regulatory Compliance throughout the R&D Process,” CBI Compliance Congress for Specialty Products, Boston, Massachusetts (September 2016)
- Speaker, “Navigating Compliance and Legal Risks Impacting Distribution and Data Management,” CBI Specialty Product Distribution and Dispensing Optimization, Philadelphia, Pennsylvania (October 2015)
- Panelist, “The FCPA and Beyond: Navigating Global Compliance Risks and Government Investigations in the New International Economy,” Association of Corporate Counsel, Boston, Massachusetts (October 2015)
- Speaker, “Managing HCP Engagements to Avoid Kickback Allegations,” CBI Compliance Congress for Specialty Products, Boston, Massachusetts (September 2015)
- Co-author, “FDA Issues New Warning Regarding Compounded Ketamine,” *Health Care Law Today* (October 26, 2023)
- Co-author, “DTC Promotional Labeling and Advertisements: Quantitative Efficacy Wins Over FDA in Final Guidance on Presenting Risk Information,” *Health Care Law Today* (September 11, 2023)
- Co-author, “Regulation of Digital Health Products by FDA,” *Health Care Law Today* (July 6, 2023)
- Co-author, “Reproductive Health: Over the Counter Birth Control Pill Supported by FDA Advisory Committees,” *Health Care Law Today* (May 31, 2023)
- Co-author, “Gender Affirming Care Restricted Under Missouri Bill,” *Health Care Law Today* (May 16, 2023)
- Co-author, “DEA Extends Telemedicine Flexibilities for Prescribing of Controlled Medications,” *Health Care Law Today* (May 10, 2023)
- Co-author, “FDA’s New Guidance Proposes Flexible Use of AI in Medical Devices,” *Health Care Law Today* (May 10, 2023).
- “Florida’s Bill Targeting Gender Affirming Care Impacts Minors and Adults,” *Health Care Law Today* (May 9, 2023)
- “FDA Publishes Framework for Digital Health Technologies in Clinical Trials,” *Health Care Law Today* (April 3, 2023)
- “Migraine Company Fails to Avoid Own Headache: Jet Medical and Others to Pay $745,000 to Resolve Allegations that Medical Device was not Approved or Cleared before Commercialization,” *Health Care Law Today* (January 11, 2023)
- Quoted, “3 key FDA topics for medtechs in 2022,” *Medtech Dive* (February 1, 2022)
- Quoted, “No Surprises Act implementation includes telehealth,” *Healthcare Finance* (January 25, 2022)
- “FDA Addresses the Role of Digital Health Technology in Clinical Trials,” *Health Care Law Today* (January 11, 2022)
- “FDA Issues Latest Draft Guidance on the Use of Real-World Data and Evidence to Support Regulatory Decision-Making for Drug and Biological Products,” *Health Care Law Today* (December 28, 2021)
- “3D Printing Medical Device at the Point of Care – FDA Invites Feedback,” *Health Care Law Today* (December 16, 2021)

- "CMS Changes Course by Repealing the Medicare Coverage of Innovative Technology and Definition of Reasonable and Necessary Rule Due to Insufficient Beneficiary Protections," *Health Care Law Today* (November 21, 2021)
- "COVID-19 Lab Tests: HHS Withdraws Policy Limiting FDA's Review, and FDA Issues an Updated Policy Requiring EUAs," *Health Care Law Today* (November 15, 2021)
- "FDA Calls for Repeating Clinical and Bioanalytical Studies," *Health Care Law Today* (October 26, 2021)
- "OTC Hearing Aids: FDA Paves the Way in its Proposed Rule," *Health Care Law Today* (October 21, 2021)
- "PhRMA Code Update Clarifies and Tightens Key Provisions Associated with Speaker Programs," *Health Care Law Today* (August 13, 2021)
- "A Target on Telehealth: Government Action Against Telehealth Fraud in the Wake of COVID-19," *American Health Law Association* (July 14, 2021)
- "Latest Open Payments Data Released Under Heightened Government Scrutiny," *Health Care Law Today* (July 8, 2021)
- "Florida Ends Telehealth Waivers; Department of Health Issues Update," *Health Care Law Today* (July 2, 2021)
- "The Role of Telehealth in Decentralized Clinical Trials," *Journal of Health Care Compliance* (May 18, 2021)
- "Clinical Trials: Does FDA's Notice to Acceleron Signal a New Era of Enforcement for Results Reporting?," *Health Care Law Today* (May 7, 2021)
- "Telehealth Legal and Regulatory Issues," Chapter in *Telemedicine: Overview and Application in Pulmonary, Critical Care, and Sleep Medicine* (April 1, 2021)
- "The Future Looks Bright for Telehealth…Mostly," American Health Law Association's *Health Law Weekly* (March 5, 2021)
- "Round Two – FDA Issues Emergency Use Authorization for Moderna's COVID-19 Vaccine," Coronavirus Resource Center: Back to Business (December 21, 2020)
- "Sunshine Act Reporting Update: De Minimis Amounts," Health Care Law Today (November 18, 2020)
- Quoted, "FDA to stop reviewing COVID-19 lab tests, raising concerns in Congress," BioCentury (October 7, 2020)
- Quoted, "Can Virtual Trials Maintain Their Momentum After COVID?", *Clinical Leader* (September 17, 2020)
- "Telehealth Today and in a Post-COVID-19 World," *Health Care Law Today* (September 1, 2020)
- "EUAs for LDTs no Longer Required, but at the Expense of PREP Act Immunity," *Health Care Law Today* (August 24, 2020)
- "COVID-19: FDA Issues Template for Over-the-Counter At-Home Testing," *Health Care Law Today* (July 30, 2020)
- "COVID-19: FDA Clears Path for Test to Screen Asymptomatic Individuals," *Coronavirus Resource Center: Back to Business* (July 23, 2020)

- "HCP Conflicts of Interest: Virtual Informational Sessions – With Lunch – Supported by PhRMA During Declared Emergencies," *Coronavirus Resource Center: Back to Business* (July 15, 2020)
- "Telehealth in the Wake of COVID-19," *Journal of Health Care Compliance* (May 18, 2020)
- "FDA Increases Scrutiny of COVID-19 Serology Tests: What Commercial Manufacturers Need to Know," *Coronavirus Resource Center: Back to Business* (May 6, 2020)
- "Episode 10: Telehealth in the Time of COVID-19," *Health Care Law Today Podcast* (May 5, 2020)
- "Episode 9: Clinical Trails in the Time of COVID-19," *Health Care Law Today Podcast* (April 29, 2020)
- "COVID-19: CMS Issues Telehealth Guidance for State Medicaid and CHIP Programs," *Health Care Law Today* (April 28, 2020)
- "COVID-19: Idaho Governor Suspends More Regulations Relating to Telehealth and Medical Licensing," *Health Care Law Today* (April 13, 2020)
- "COVID-19: New York's Medicaid Expansion of Telehealth During the State of Emergency," *Health Care Law Today* (March 31, 2020)
- "Telehealth (Massachusetts): COVID-19 Inspires Relaxed Telemedicine Technology Requirements and Mandates Payment Parity," *Health Care Law Today* (March 18, 2020)
- "Telemedicine Compliance: The Practice Requirements," *Journal of Health Care Compliance* (March 1, 2020)
- "Clinical Decision Support Software: FDA's Risk-based Approach," *Asian Hospital and Healthcare Management* (March 1, 2020)
- "2020 Business of Personalized Medicine Summit: Break Through to Solutions in the Birthplace of Biotechnology," *Personalized Medicine Bulletin* (February 18, 2020
- "Telehealth: Massachusetts' Proposed Act to Improve Health Care by Investing in Value," *Health Care Law Today* (January 29, 2020)
- "Drug Pricing Transparency: Massachusetts' Proposed Reporting Requirements," *Health Care Law Today* (December 19, 2019)
- "Clinical Research Compliance Manual: An Administrative Guide" (November 21, 2019)
- Quoted, "FDA releases revised draft guidance on CDS software, final guidelines on 'device' definitions for software such as wellness apps," *MobiHealthNews* (September 26, 2019)
- "Fact or Fallacy: Is Telehealth Here to Stay?", *HealthTech* (August 1, 2019)
- "Blockchain: A Tool With a Future in Healthcare," *Health Care Law Today* (July 18, 2019)
- "Pharmacies: DOJ Wins TRO to Immediately Suspend Registration for Controlled Substances," *Health Care Law Today* (March 28, 2019)
- Quoted, "New Medicaid Telehealth Standards in Massachusetts Draw Criticism," *mHealth Intelligence* (March 5, 2019)
- "The Good and the Bad of the New MassHealth Telemedicine Rule," *Health Care Law Today* (March 4, 2019)
- Quoted, "Biosimilars, diabetes and HCV drug uptake expected to spike with HHS changes restricting safe harbor protection for PBMs and drug manufacturers, experts say," *BioPharm Insight* (February 20, 2019)
- Quoted, "Massachusetts Push for Telehealth Parity," *Politico* (February 5, 2019)

- "HHS Proposes New Rules to Eliminate Drug Rebates and Encourage Direct Discounts for Federal Beneficiaries," *Health Care Law Today* (February 1, 2019)
- Quoted, "FDA looks to De Novo Pathway Model As it Unveils Updates to Pre-Cert Program," *MobiHealthNews* (January 8, 2019)
- "ACA Strike-Down: Salvaging the BPCIA via Severability," *Health Care Law Today* (January 2, 2019)
- Quoted, ACA Repeal Wouldn't Stop Transition to Value-Based Payment, Efforts to Lower Drug Spending," *Modern Healthcare* (December 19, 2018)
- Quoted, "Proposed Framework Lessens FDA's Regulatory Requirements for Prescription Drug Companion Apps," *MobiHealthNews* (November 19, 2018)
- "cGMP Violations Should Not Be Used as a Basis for FCA Actions Absent Fraud," 38 *Seattle U. L. Rev*. 37 (2014)
- "Limits on cGMP Violations under the FCA," *2 Fraud & Abuse*, 1 (2013)
- "The Misuse of the FCA to Enforce cGMP (Current Good Manufacturing Practice) Violations," 6 No. 24 *International In-House Counsel Journal*, 1 (2013)
- "Why FDCA § 505(u) Should Not Concern Us Greatly," 15 *Michigan Telecommunications and Technology Law Review*, 453 (2009)
- "*Georgia v. Ashcroft*: A New Statistical Model," 13 Georgetown Public Policy Review 45 (2007-08)

Sectors

- Food & Beverage
- Food Regulatory Compliance
- Health Care & Life Sciences
- Pharmaceuticals
- Racial Justice & Equity
- Telemedicine & Digital Health

Practice Areas

- Behavioral Health
- Corporate
- FDA Regulatory
- Government Enforcement Defense & Investigations
- Government Solutions
- Health Care
- Health Care Regulatory
- Israel

Education

- University of Michigan Law School (J.D., 2007)
    - Executive Editor, *Michigan Journal of Law Reform*

    - Executive Symposium Editor, *Michigan Telecommunications and Technology Law Review*
    - Recipient, the Book Award, FDA Law
- Bryn Mawr College (2002)
    - Certificate in Post-Baccalaureate Pre-Medical Studies
- Smith College (A.B., 1997)
    - Physiological Psychology, with a minor in Neuroscience

Admissions

- Massachusetts