



Kate Hardey

Partner

Health Care

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Kate Hardey combines deep industry knowledge with a focus on delivering effective client solutions. Kate is a trusted leader in navigating the regulatory and transactional challenges affecting companies in the health care provider, life sciences and food industry sectors, including pharmaceutical and medical device manufacturers, laboratories, pharmacies, physician groups, hospital systems, food manufacturers and related food industry entities.

Driving success in health care transactions

Kate is a trusted advisor to clients in the life sciences and food industries, and health care provider and health care services sectors, delivering tailored guidance on complex regulatory matters and high-stakes corporate transactions. She is frequently sought after by private equity firms and strategic acquirers for her counsel in major acquisitions and mergers. Clients with products regulated by the US Food and Drug Administration (FDA), including human and animal pharmaceuticals, medical and digital health devices, cosmetics, over-the-counter (OTC) medications, dietary supplements, and food and beverage products, rely on Kate's extensive experience with transactional strategies and regulatory knowledge to navigate complex legal and regulatory frameworks effectively.

In addition to her work on complex transactional matters, Kate delivers comprehensive support across the entire FDA-regulated product lifecycle, guiding clients through product development, clinical trials, product classification, manufacturing, sales and marketing strategies, and recalls with precision. Kate also advises on a broad spectrum of health care regulatory issues, including pharmacy compliance, corporate practice of medicine and dentistry, and fraud and abuse concerns. She guides clients through critical regulations such as the Anti-Kickback Statute, the Stark Law and other legal frameworks. Her proactive, client-focused approach ensures seamless navigation through even the most complex regulatory challenges.

Practices

- Health Care
- Health Care Transactions
- Health Care Finance
- Health Care Regulatory and Compliance
- Health Care Services Private Equity
- Hospital-Physician Relations and Medico-Legal
- Mergers and Acquisitions
- Private Credit
- Private Equity

Industries

- Pharmaceutical and Life Sciences

Education

- JD, Catholic University of America
Columbus School of Law, *cum laude*
- MS, Marymount University, Healthcare
Administration
- BA, George Mason University

Bar Admissions

- District of Columbia
- North Carolina
- Virginia

Community Involvements

- Domestic Violence Legal Empowerment and Appeals Project (DV LEAP), Board Member (2014–2022)

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A strategic partner with industry experience

Kate's distinctive background, rooted in hands-on industry experience, distinguishes her as an exceptional advisor. Her tenure as legal counsel within a large hospital system gives her unparalleled insight into hospital board dynamics and leadership teams and allows hospitals to benefit from her hands-on familiarity with physician contracting, medical staff compliance, pharmacy operations, patient privacy and patient care issues. Kate's time managing a physician practice and serving as an emergency department administrator at a top-tier academic medical center further enhances her ability to understand and assess clients' needs. From billing and coding compliance to managed care contracting, financial and strategic planning, emergency preparedness and Emergency Medical Treatment and Labor Act (EMTALA) compliance, Kate's comprehensive knowledge ensures her clients stay ahead of regulatory and operational challenges.

As former senior regulatory counsel for a prominent middle-market health care lender, Kate developed a sophisticated understanding of the regulatory risks associated with transactions involving pharmaceutical, medical device, technology and health care provider entities. She enables lenders to efficiently and effectively navigate complex lending transactions by identifying and mitigating regulatory risks, ensuring streamlined due diligence and facilitating effective lender documentation.

Kate frequently speaks on health care regulatory trends and has been quoted in media outlets such as *The Wall Street Journal*.

Representative Experience

Life Sciences

- Represented a holding company in its pending \$193.5 million sale of a provider of vitamins and nutritional supplements.*
- Represented multiple financial institutions as placement agents in connection with the \$260 million PIPE financing commitment for Helix Acquisition Corp. II (NASDAQ: HLXB), a SPAC sponsored by affiliates of an investment firm, to combine with a clinical-stage biopharmaceutical company advancing novel small-molecule therapeutics.*
- Represented a private equity firm in its acquisition of a provider of generic oral liquid medicines.*
- Represented a therapeutics company in the up to \$2.5 billion pending sale of a treatment program for breast cancers in clinical trials to a pharmaceutical company.*

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- Represented a private equity firm-backed health care services company in its pending acquisition of the unit-dose packaging business of a publicly traded global health care company.*
- Represented a medical device company in the sale of its respiratory diagnostic business unit to another medical device company.*
- Represented a pharmaceutical company in its \$3.2 billion acquisition of a biotechnology company.*
- Represented a global provider of mission-critical flow creation and industrial solutions in the \$2.325 billion acquisition of a manufacturer for the pharmaceutical industry from an investment firm.*
- Represented a pharmaceutical company in its \$520 million acquisition of a provider of protein-based animal health therapeutics.*
- Represented a private equity-backed company specializing in clinical research services in its \$115 million acquisition of a provider of imaging biomarker services.*
- Represented an animal health company in its \$350 million acquisition of medicated feed additive and water-soluble product portfolios from a global animal health company.*
- Represented a private equity firm in its \$700 million acquisition of a medical device components business from a sustainable technologies and specialty chemicals company.*
- Represented a diversified manufacturing company in the sale of its business unit specializing in interconnect technologies for various industries, including aerospace, defense, and medical, to a publicly traded global provider of interconnect and sensor solutions.*
- Represented a pharmaceutical company in its \$8.7 billion acquisition of a neuroscience drug company.*
- Represented a private equity firm in its acquisition of a platform for pharma commercialization and market access.*
- Represented a provider of generic and specialty pharmaceutical products in its sale to a pharmaceutical company.*
- Represented a pharmaceutical company in its \$1.4 billion acquisition of a radiopharmaceutical company.*
- Represented a private equity firm in its investment in a clinical research site platform serving pharmaceutical and biotechnology companies and contract research organizations.*
- Represented a private equity firm in its investment in a provider of strategic services across the entire life sciences product cycle.*

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- Represented a private equity firm in its pending \$627 million acquisition of a provider of medical device and in vitro diagnostic technologies.*
- Represented a private equity firm in its acquisition of a contract development and manufacturing organization of branded over-the-counter products.*
- Represented a private equity firm in the recapitalization of a contract development manufacturing organization (CDMO) of non-sterile liquid and semi-solid dosage forms.*

Health Care Technology

- Represented a private investment firm in its investment in a provider of vascular access and medication management products.*
- Represented a private equity firm in its acquisition of a provider of a consumer health & wellness platform for orthotics and other footcare-focused solutions.*
- Represented a health care technology company in its acquisition of a provider of language interpretation services.*
- Represented a health care technology company on the proposed \$180 million acquisition of a leading provider of tech-enabled, healthcare-focused language interpretation services.*
- Represented a private equity firm in its \$680 million acquisition of a provider of health and wellness solutions.*

Food & Beverage

- Represented a private equity firm in its acquisition of a provider of bakery products for quick service restaurants and in-store retail bakeries.*
- Represented a private equity-backed pet wellness company in its sale of a production facility in Indiana to a pet food producer.*
- Represented an investment firm in its acquisition of a provider of pet supplements.*
- Represented a private equity firm in its acquisition of a provider of sparkling water, teas and lemonades, hard seltzers and mocktails.*
- Represented a middle-market private equity firm in the sale of a provider of disposable food safety and hygiene-oriented products for the foodservice industry.*
- Represented a private equity firm in its investment in a brand of premium condiments and truffle-infused products.*

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- Represented a private equity firm in its pending EUR 16 billion acquisition of a provider of over-the-counter drugs and vitamins, minerals and supplements.*
- Represented a New York-based private equity firm in its acquisition of a super fruit bowl franchise restaurant.*

*Experience prior to Katten

Recognitions

Recognized or listed in the following:

- American Lawyer Media
 - Most Effective Deal-Maker, 2023
- The M&A Advisor
 - Healthcare/Life Sciences Deal of the Year, 2022
- *North Carolina Lawyers Weekly*
 - Leaders in the Law, 2020
- *National Law Journal*
 - Cannabis Law Trailblazer, 2020

News

- Anthony Del Rio and Kate Hardey's Arrival at Katten Captures Media Spotlight (June 27, 2025)
- Katten Taps Anthony Del Rio and Kate Hardey to Join Leading Health Care Practice (June 3, 2025)

Publications

- Recent Listeria Outbreaks Hold Key Compliance Lessons | *Law360* (November 21, 2024)

Presentations and Events

- 6th Annual Clinical Trial Agreement Conference (August 21 - 22, 2025) | *Speaker* | *Navigate the Intricacies of Company Mergers and Their Impact on CTAs*