



Ricky C. Benjamin

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Overview

Ricky Benjamin is an experienced health care and life sciences lawyer and former general counsel who focuses his practice on advising pharmaceutical, biotechnology, medical device, and diagnostic companies on regulatory, compliance, transactional, and litigation matters.

Ricky has served as a trusted business and risk management adviser to clients for more than three decades. A seasoned health care attorney and litigator, Ricky has a unique combination of in-house and private practice experience and a deep understanding of the dynamics of the business of science. His depth of experience allows him to guide clients from all angles — commercialization, product launch, regulatory compliance, and litigation — and speak the language of the scientific, technical, and medical disciplines, with the overarching goal of identifying, quantifying, and mitigating risk.

Regulatory Compliance: Ricky provides comprehensive guidance on navigating the complex web of federal and state laws and regulations, including the federal anti-kickback statute, physician self-referral laws (Stark), the Health Insurance Portability and Accountability Act (HIPAA), and data privacy and cybersecurity regulations. He represents companies with international and domestic presence before the Food and Drug Administration (FDA). He assists clients with the development, manufacture, marketing (premarket approval applications, 510(k) clearances), and regulatory compliance, including labeling and recalls of medical devices, drugs, and cosmetics. Ricky also represents manufacturers in supply chain matters related to these regulated products, including supply agreements and software licensing agreements (SaaS, SiMD, SaMD, and IoT). Ricky represents clients in all phases of the product life cycle, including formulation and marketing authorizations, post-market compliance, certification, and manufacturing best practices. He also advises on regulatory issues at the intersection of health services innovation, digital health, and emerging technologies, including artificial intelligence and machine learning.

Litigation and Risk Management: Ricky has extensive litigation experience in the areas of medical malpractice defense, qui tam litigation, mass tort and product liability, and risk management counseling involving the Foreign Corrupt Practices Act (FCPA), the Federal Food, Drug, and Cosmetic Act (FDCA), and the Federal Tort Claims Act (FTCA), as well as involving the Federal Trade Commission (FTC), the Department of Justice (DOJ), the Office of Inspector General (OIG), and the Centers for Medicare & Medicaid Services (CMS). His experience makes him uniquely suited to anticipate, identify, and defend product liability actions in such a way as to marshal the facts to minimize later qui tam actions by private plaintiffs or regulatory enforcement actions by the government. With a robust litigation background, Ricky has litigated more than 200 cases, defended or responded to more than 50 government investigations, and conducted more than 75 internal audits as part of managing global privileged investigations under the FCPA amid allegations of fraud, waste, and abuse.

Transactional Matters: Ricky's transactional practice encompasses specialized due diligence of life sciences transactions, including deal structuring, representations and warranties, and compliance with regulatory requirements associated with mergers and acquisitions and in-licensing agreements. He possesses a deep understanding of the intricacies involved in supply chain transactions, capital equipment agreements, and cloud-based agreements, particularly within the life sciences industry.

Ricky's diverse background includes roles as general counsel for dental and surgical practices, inhouse regional head of litigation for a global insurance company, lead national trial counsel for opioid litigation, and professor of health care law and ethics at Tulane University. In addition to his law degree, Ricky has a bachelor's degree in computer science and worked as a software programmer before attending law school.

Experience

Biometric Information

Counseled clients on the applicability of the General Data Protection Regulation and the
California Consumer Privacy Act on their business operations involving the collection of
identifying data related to consumer spending patterns, under the act's definition of biometric
information as including physiological, biological and behavioral characteristics, which includes
the traditional fingerprint and retinal scan as well as keystroke, gait patterns, sleep, health and
exercise data, that contain identifying information.

Biopharmaceuticals - Qui Tam Litigation

- Defended a pharmaceutical company in federal court against allegations that it paid kickbacks to Medicare beneficiaries in violation of the anti-kickback statute by using a charity as an illegal conduit to cover the copays of Medicare patients who were taking the company's pulmonary arterial hypertension drugs.
- Defended a drug wholesale company and its subsidiaries in a federal court action against
 allegations under the False Claims Act (FCA) arising from their operation of a facility that allegedly
 improperly repackaged oncology-supportive injectable drugs into pre-filled syringes and
 distributed those syringes to physicians treating cancer patients
- Defended a drug company's wholly owned subsidiary in federal court against allegations that it illegally distributed misbranded drugs from a facility that was not registered with the Food and Drug Administration (FDA).

FTC Investigation of Privacy Issues

Counseled a medical laboratory that performed cancer-detection testing services for doctors, that ran afoul of the FTC when it stored its patient information on a peer-to-peer file-sharing network. The lab exposed the personal information of approximately 10,000 consumers, including the collection of such information as test results, Social Security numbers, and insurance data. The FTC purported to investigate, regulate and sanction the client through its Section 5 authority to take action against companies over alleged lax data security practices, where it argued the disclosure of medical information "is in and of itself a substantial injury", and thus constituted a cognizable claim under Section 5 of the FTC Act.

FTC Investigation

 Defended a home health care facility in an investigation by the FTC amid allegations of an unfair trade practice due to allegations of having inadequate data security protocols following a data breach, by sophisticated hackers.

Health Care M&A

 Oversaw the acquisition of a supplier, developer, and producer of turn-key biomanufacturing systems and production-scale bioreactors based around single-use components. This acquisition allowed the client to expand its health care offering of products and services for the manufacture of biopharmaceuticals like recombinant proteins, antibodies, and vaccines. Total funding amount was \$50.5 million.

International Health Care M&A

Represented client in sale of nurse call business to global solutions provider for \$22 million, with a
possible earn-out up to \$6 million. The nurse call business generated \$20 million in revenues with
margins similar to the acquiror. The acquisition strengthened the acquiror's existing nurse call
business and allowed it to provide its customers with better features and functionality in
combination with its mobility systems.

Joint Venture Agreement

Counseled a medical technologies and services company in a joint venture agreement between
the company and Microsoft Corp. which created a 50/50 joint venture aimed at enabling health
systems and professionals to use real-time, organization-wide intelligence to improve health care
quality and patient experience, offering innovative health care solutions, including an open
platform and tools, allowing software developers around the world to address the complexities of
population health.

Medical Device M&A

Represented client in the \$167 million, all cash sale of medical products unit to a manufacturer
and marketer of proprietary disposable devices used primarily in cardiology, radiology, and
endoscopy equipment. The deal added to expand the acquiror's existing OEM business, which
was valued at \$100 million in annual revenues.

Medical Device Manufacturer Divestiture

 Counseled medical device manufacturer through negotiating, drafting, and closing agreements involving the strategic and operational planning process for divestiture of a business line involving a Canadian distributor.

Medical Device Regulatory Counseling

- Advised global medical technology company on multistate DMEPOS licensure requirements and multistate Stark and anti-kickback laws.
- Advised global medical device manufacturer on how to set up its organization as a certified/approved DME provider and supplier to sell and market its devices in multiple states, amid the states' varying qualifying criteria.

Medical Technology Company - Compliance

 Counseled a medical technologies and device manufacturer on regulatory requirements impacting big data/data analytics, wearable devices, mobile health, personalized medicine, and artificial intelligence/machine learning.

Medical Technology Company - Transactions

 Drafted cloud-based services agreements, including SaaS, SaaD, and SaMD, and counseled on regulatory requirements implicated by those transactions.

OIG Investigation

• Defended a health care system in a drug diversion investigation by OIG.

Opioid Litigation

• Oversaw national opioid litigation for assessment of liability exposure, strategic defense, and best practices surrounding prescribing opioids.

Product Liability Litigation

 Defended medical device manufacturer of ultrasound equipment in product liability action amid disputed FDA categorization of device as Class II or III medical device.

Qui Tam Litigation

- Defended health system amid allegations of physician self-referral violations and intentional billing errors in attempt to maximize profits in violation of anti-kickback statute.
- Defended permanently excluded urologist against claims of overbilling in provision of telemedicine services.
- Defended clinical laboratory client against allegations of anti-kickback violations, wire fraud, mail fraud, and conspiracy to commit wire fraud and mail fraud, based on whistleblower complaint of stolen home test kits for the coronavirus and then never providing the test results.
- Defended physician excluded from Medicare and Medicaid for three years for misrepresentations
 made to IRS relating to private benefits and inducements received, which gave rise to submission
 of false claims in violation of the private inurement and beneficiary inducement provisions of the
 anti-kickback statute.

Qui Tam and Criminal Investigation

 Defended a home health care facility in a qui tam and criminal investigation amid allegations of inappropriate staffing ratios allegedly leading to a wrongful death claim where one patient killed another patient after having been allegedly prescribed a medication dosage insufficient to curtail behavior.

Areas of Focus

Practices

- Health Care
- Business Transactions
- Cybersecurity and Privacy
- False Claims Act, Qui Tam, and Whistleblower Defense
- Mass Tort and Product Liability
- Technology
- White Collar Crime & Government Investigations

Industries

- Health Care
- Technology

News

01.29.2024

Ricky Benjamin Featured in Attorney at Law Magazine: "Lawyer Ricky C. Benjamin Joins Carlton Fields Health Care Practice"

01.29.2024

Leading Life Sciences Lawyer Ricky C. Benjamin Joins Carlton Fields Health Care Practice

01.29.2024

Ricky Benjamin Featured in Bloomberg Law: "Carlton Fields Adds Ricky C. Benjamin as Shareholder in Atlanta"

01.29.2024

Ricky Benjamin Featured in Law360: "Akerman Health Pro Jumps to Carlton Fields in Atlanta"

Recognition

The National Black Lawyers Top 100 (2020)

Professional and Community Involvement

- American Health Lawyers Association
- National Association of Health Services Executives

Credentials

Education

- University of Iowa College of Law (J.D., 1990)
- Southern University and A&M College (B.S., 1985)

Bar Admissions

- Colorado
- Georgia
- Wisconsin

Court Admissions

- · U.S. District Court, District of Colorado
- U.S. District Court, Northern District of Georgia
- U.S. District Court, Middle District of Georgia
- U.S. District Court, Eastern District of Wisconsin
- U.S. Court of Appeals, Seventh Circuit
- · U.S. Court of Appeals, Tenth Circuit
- U.S. Court of Appeals, Eleventh Circuit
- U.S. Supreme Court