

# Health Care & Life Sciences

Health care and life sciences is inarguably one of the largest, most heavily regulated, and fastest-growing industries in the U.S. economy. It is also utterly unique. Health care and life sciences companies do not function simply to maximize returns, and the standard economic forces of supply and demand do not apply. Ultimately, every player in this market—whether a hospital, biotechnology company, nursing home, or medical equipment manufacturer—is responsible for helping people lead longer and healthier lives.

To be effective, advocates for the health care and life sciences industry must integrate an awareness of and commitment to this underlying responsibility into every element of their work. The members of Cozen O'Connor's health care and life sciences industry team understand this social mission as well as its legal, political, macroeconomic and business consequences for our clients. Attorneys at the firm have been providing excellent counsel to health care and life science companies for decades.

Our client base includes a diverse array of companies. In the health care sector, we serve leading pharmaceutical companies, hospitals, health care systems, medical equipment manufacturers and suppliers, assisted living facilities, academic institutions, insurers and physician groups. In the life sciences sector, we serve drug developers, biotechnology companies, medical device manufacturers and cutting-edge startups.

For health care and life sciences clients, it is essential that their attorneys have deep industry knowledge. Good commercial litigators or corporate lawyers can serve a chain of shoe stores just as capably as a chain of pizza parlors, but that does not mean they can serve a chain of hospitals. The health and life sciences field is so heavily regulated that all legal work in this arena must be grounded in a specific and sophisticated understanding of health laws. At Cozen O'Connor, we have litigators, transactional lawyers and corporate counselors who are both leaders in their legal disciplines and masters of this complex and ever-changing statutory regime.

## SERVICE AREAS

### Litigation

- Handle third-party payer litigation and reimbursement proceedings
- Represent clients in fraud, abuse, Stark Law and False Claims Act cases
- Conduct internal investigations and respond to enforcement acts by federal and state agencies
- Represent health care and life sciences companies in intellectual property, employment, antitrust and other commercial litigation

### Transactional

- Arrange mergers, acquisitions, consolidations, divestitures, workouts and restructurings
- Negotiate joint ventures, alliances and co-management arrangements
- Resolve antitrust, tax and bankruptcy issues for health care and life sciences organizations
- Arrange financings through public offerings, bonds, loans and other investment vehicles
- Conduct major real estate deals for industry clients

### Regulatory

- Advise on privacy, confidentiality, HIPAA compliance and safety laws
- Handle Medicare, Medicaid and other third-party reimbursement matters
- Develop and assess regulatory compliance programs for health care and life science clients



**R. Christopher Raphaely**

Co-Chair, Health Care

[craphaely@cozen.com](mailto:craphaely@cozen.com)

Phone (215) 665-2099

Fax (215) 665-2013

### Related Practice Areas

- Antitrust
- Biologics/Biosimilars
- Corporate
- Emerging Business & Venture Capital
- Employee Benefits & Executive Compensation
- Employment Litigation
- Government Relations - Cozen O'Connor Public Strategies
- Hatch-Waxman Litigation
- Health Care
- Immigration Policy & Strategy
- Institutional Response Group
- Intellectual Property
- Italy Practice
- Labor & Employment
- Labor Relations & Disputes
- Mergers & Acquisitions
- Patents
- Public & Project Finance
- Tax
- Technology, Privacy & Data Security
- Trade Secrets, Restrictive Covenants, and Computer Abuse
- Trademark & Copyright

- Counsel clients on employee benefits, credentialing and executive compensation strategies

## RELATED PRACTICES

- Health Law
- Labor & Employment
- Employee Benefits & Executive Compensation
- Antitrust
- Real Estate
- Public & Project Finance
- Intellectual Property
- Product Liability
- Cozen O'Connor Public Strategies, LLC

## Experience

Represented one of the country's largest post-acute care providers in connection with the \$84 million sale of its hospice and home health subsidiaries to a nationwide network of community-based hospice and palliative care programs.

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Represent health plan in ERISA action alleging improper denial of benefits.

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Successfully brought motion to dismiss a complaint alleging denial of benefits under an ERISA-exempt health policy.

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Represented Morphotek, Inc., a biotech company, in multiple rounds of financing, including more than \$40 million of venture capital financings from a group of prominent venture funds, including SR One, Limited, Forward Ventures, China Development Industrial Bank, Rock Maple Ventures, Burrill & Co., CB Health Ventures, and Flagship Ventures to the subsequent \$350 million acquisition of Morphotek by Japanese health care research and development firm ESAI Corporation.

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Lead counsel in damage phase of a patent infringement action regarding Sandoz's ANDA to make a generic version of Pfizer's seizure and neuropathic pain product, Neurontin®, the active ingredient of which is gabapentin. The case settled during the pre-trial phase and after successful Motions in Limine by Sandoz.

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Represented Apotex Inc. in a patent infringement action regarding Apotex's ANDA to make a generic version of AVODART® (dutasteride). Settled prior to trial.

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Handled a patent infringement action regarding Sandoz's ANDA to make a generic version of Alcon's eye allergy product Pataday®, the active ingredient of which is olopatadine hydrochloride.

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Handled a patent infringement action regarding Sandoz's ANDA to make a generic version of Pfizer's antimuscarinic tablet Detrol and Detrol LA®, the active ingredient of which is tolterodine tartrate.

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Handled a patent infringement action regarding Sandoz's ANDA to make a generic version of Pfizer's antifungal medication VFEND®, the active ingredient of which is voriconazole.

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Represented Sandoz Inc. in a patent infringement action regarding Sandoz's ANDA to make a generic version of Alcon's eye allergy product PATANOL® (olopatadine hydrochloride). Case settled.

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Represented Sandoz Inc. in a patent infringement action concerning Sandoz's ANDA to make a generic version of Abbott's NIASPAN® (Niacin) controlled-release tablets. Case settled prior to trial.

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Represented Sandoz Inc. in a patent infringement action concerning Sandoz's ANDA to make a generic version of Abbott's TRILIPIX® (Fenofibric Acid) capsules. Case settled prior to trial.

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Represented Innopharma, Inc. and Amneal Pharmaceuticals, Inc. in patent infringement actions concerning our clients' ANDAs to make generic versions of Spectrum's FUSILEV® (Levoleucovorin) Injection product.

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Represented Sandoz Inc. in patent infringement action concerning Sandoz's ANDA to make a generic version of Helsinn's anti-nausea product Helsinn's ALOXI® (Palonosetron Hydrochloride) injection product. Case settled prior to trial.

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Represented Sandoz Inc. in a patent infringement action concerning Sandoz's ANDA to make a generic version of Roche's VALCYTE® (Valganciclovir Hydrochloride) capsule product. Case settled prior to trial.

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Represented Sandoz Inc. in a patent infringement action concerning Sandoz's ANDA to make a generic version of Shire's ADHD product INTUNIV® (Guanfacine Hydrochloride). Case settled prior to trial.

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Represented Apotex Inc. and Apotex Corp. in a patent infringement action concerning Apotex's ANDA to make a generic version of Pfizer's PRISTIQ® (Desvenlafaxine) extended-release oral tablet products. Case settled prior to trial.

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Represented Apotex Inc. in a patent infringement action regarding Apotex's ANDA to make a generic version of ACULAR LS® (0.4% ketorolac tromethamine). Led the negotiations that resulted in a successful settlement of the matter after the close of expert discovery.

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Trial counsel for Apotex Inc. and Apotex Corp. in a patent infringement action regarding Apotex's ANDA to make a generic version of LYSTEDA® (tranexamic acid). After a two week trial, received a favorable decision of non-infringement on all three patents in-suit. Successfully argued on appeal with the Federal Circuit affirming the trial court decision.

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Represented Sandoz Inc. in a patent infringement action concerning Sandoz's ANDA to make a generic version of Abbott's ZEMPLAR® (Paricalcitol) oral capsule product. Case settled prior to trial.

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Represented Mylan Pharmaceuticals, Inc. in a patent infringement action concerning Mylan's ANDA to make a generic version of Pfizer's CADUET® (Atorvastatin Calcium and Amlodipine Besylate) oral tablet products. Case settled prior to trial.

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Represented Actavis in a patent infringement action concerning Actavis's ANDA to make a generic version of King's pain product AVINZA® (Morphine Sulfate) oral capsule products. Case settled prior to trial.

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Represented Sandoz Inc. in a patent infringement action regarding Sandoz's ANDA to make a generic version of Merck's anti-nausea product EMEND® (aprepitant).

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Represented our client, Sandoz Inc. in a patent infringement action regarding Sandoz's ANDA to make a generic version of Alcon's eye allergy product PANTANOL® (olopatadine hydrochloride).

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Represented Sony Corporation of America in its acquisition of iCyt Mission Technology, Inc., a leading producer of high-performance cell sorters used for stem cell and disease research.

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Represented Apotex Inc. in a patent infringement action regarding Apotex's ANDA to make a generic

version of Sanofi-Aventis' anticancer product TAXOTERE®, the active ingredient of which is docetaxel. Following a two-week trial, obtained an order for Apotex striking down the patents-in-issue as invalid as obvious and unenforceable due to Sanofi-Aventis' inequitable conduct in procuring the patents. Successfully argued on appeal with the Federal Circuit affirming trial court decision (April 2012). Of import is that inequitable conduct defense remains viable in ANDA litigations because of this ruling.

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Represented Apotex Inc. in a patent infringement action regarding Apotex's ANDA to make a generic version of Wyeth's anti-depressant product EFFEXOR XR® (venlafaxine hydrochloride). Settled on favorable terms during trial.

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Represented Sandoz Inc. in a patent infringement action regarding Sandoz's ANDA to make a generic version of Endo's pain product OPANA® ER (oxymorphone hydrochloride).

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Lead counsel for Sandoz Inc. in a patent infringement action regarding Sandoz's ANDA to make a generic version of Medicis' acne product SOLODYN® (minocycline hydrochloride).

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Represented seller of a 78% equity position in a physician-owned 782 bed full-service hospital in Houston.

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Represented a U.S. innovative medical device developer and distributor in acquisition of 100% equity interests of a U.S. competitor.

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Represented a global pharmaceutical company in the largest global M&A transaction as of 1996.

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Represented a German-based biotech company in a patent infringement action regarding a method for synthesizing nucleic acids.

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Represented a U.K.-based pharmaceutical packaging company in establishing U.S. operations, including engagement of distribution team and negotiation of supply agreements with pharmaceutical companies.

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Represented a U.S. life sciences company in a license and distribution transaction with a top five worldwide pharmaceutical company.

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Represented a U.S.-based medical device company in acquisition of European-based competitor.

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Represented the seller of three skilled nursing facilities in South Florida.

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Represented the seller of a skilled nursing facility in Trenton, N.J.

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Represented the seller of a skilled nursing facility in Lakewood, N.J.

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Represented the purchaser of five skilled nursing facilities in Philadelphia.

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Represented an air ambulance company in a dispute with a Medicaid managed care organization (MCO) that refused to pay more for out-of-network transportation services than the federal default rate applicable to emergency hospital services. We brought suit alleging that the default rate did not apply, that the MCO had breached an implied-in-fact contract with the company and the terms under which it participated as a Medicaid plan, and that the MCO had been unjustly enriched. After the court denied most of a motion to dismiss by defendant, the matter settled on favorable terms for our client.

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Represented a major hospital center in an arbitrated dispute with a Medicaid Managed Care Organization (MCO). Over the hospital's objection, the MCO sought to justify failures to pay for hospital services on medical necessity grounds, even though the MCO had denied the relevant claims

solely for lack of authorization. After the arbitrator ruled in the hospital's favor on this issue and a variety of others, the matter settled on favorable terms for our client.

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Represented nursing homes in New Jersey and Florida in asset sale of facilities.

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Established ambulatory surgery facilities and assisted in compliance with state and federal regulations, including Stark.

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Represented dental practices in multiple mergers and acquisitions.

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Provided counsel to device manufacturer on vendor/marketing issues.

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Served as regulatory counsel for hospice provider.

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Developed compliance programs for hospital based pharmacy and home health provider.

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Assisted medical device client in becoming compliant with Physician Payment Sunshine Act.

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Represented Portico Systems of Delaware, Inc. in its acquisition by McKesson Health Solutions, a subsidiary of McKesson Corporation (15th on the Fortune 500), for approximately \$90 million. The firm represented this company since its formation and through multiple transactions, including several investments by Safeguard Scientifics and Edison Venture Fund.

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Lead counsel for Barr Labs in a patent infringement case involving Barr's drug, TAMBACOR®.

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Served as lead trial counsel for Celgene Corporation against various internet pharmacies to stop the unauthorized sale of products, all resulting in defendants discontinuing online sales of unauthorized products.

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Served as lead trial counsel for Arora Board Review and various doctors in defense of claims of copyright infringement and breach of contract filed by the American Board of Internal Medicine.

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Defended our client, a regional hospital and health care system, when it was sued in federal court for age and national orientation discrimination by a former employee who had been terminated from his employment for theft of time. We won summary judgment on behalf of our client. We prevailed in the Court of Appeals for the Third Circuit after the former employee appealed the summary judgment decision.

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Represented national nursing home chain in Medicare Part A appeals involving "related party" (institutional pharmacy) reimbursements.

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Represented Diagnostek, Inc., a NYSE mail order pharmacy, which was subsequently acquired by Value Health (now Express Scripts) for \$500 million.

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Handled the consolidation of two healthcare systems in Pennsylvania including performing due diligence, negotiating and drafting all required definitive documents, communicating with federal and state regulators and with the Pennsylvania Attorney General's office, and obtaining private letter rulings from the Internal Revenue Service related to the consolidation.

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Represented the underwriters in structuring bond financing for six assisted living facilities in Pennsylvania, New Jersey and Delaware, including a new \$54 million campus for the Philadelphia Geriatric Center through the insurance of unrated tax-exempt bonds.

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Represented physician group practices before the New Jersey Board of Medical Examiners in connection with compliance with the New Jersey anti-referral law, commonly referred to as the

"Codey Law."

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Represented the American Hospital Association and Association of American Medical Colleges as friends of the court in *In re: Cardiac Device Litigation* (Second Circuit U.S. Court of Appeal) involving Medicare billings for services including investigational devices.

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Defended a multi-state provider of behavioral health services against a False Claims Act suit brought by the federal and state governments, and advised the client with respect to its obligations under a resulting Corporate Integrity Agreement.

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Assisted ambulatory care facility in developing patient safety program.

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Advised a physician organization on compliance with the antitrust laws in connection with negotiating managed care contracts on behalf of its member constituents.

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Prohibited Medicare program from recouping pre-petition overpayments from hospitals that have filed for bankruptcy in *In re: Universal Medical Center, 973 F.2d 1065* (3d Cir. 1992).

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Assisted a local hospital obtain training reimbursement rates from Medicare after an eight year fight from the initial administrative appeal challenging the government's interpretation of its re-audit rules to a federal case in the Third Circuit. The court ordered the government to recalculate its reimbursements without reliance on its discriminatory re-audit rule.

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Provided guidance to hospital client regarding inter-relationship of state and federal patient safety laws.

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Represented Children's Seashore House in *Children's Seashore House v. Waldman, 197 F. 654* (3d Cir. 1999), affirming constitutional claim to require state to pay Medicaid disproportionate share adjustments to out-of-state providers.

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Represented Mercy Catholic Medical Center in *Mercy Catholic Medical Ctr. v. Thompson, 380 F.3d 142* (3d Cir. 2004). Invalidating CMS audit rules used to set average per resident amount; requiring intermediaries to increase costs not previously claimed as GME expense, but verified by subsequent time studies.

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Represented New Jersey Hospital Association in *New Jersey Hospital Ass'n v. Waldman, 73 F.3d 509* (3d Cir. 1995). Challenge by New Jersey hospitals to reduction of DRG rates and adequacy of disproportionate share payments.

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Represented the debtor, the owner and manager of a 220-bed nursing home, in its Chapter 11 case in the United States Bankruptcy Court for the District of New Jersey, where we confirmed a Chapter 11 plan restructuring the client's secured debt, real-property leases, and union obligations, and enabled the Debtor's equity interests to maintain ownership of the entity, all while maintaining a consistently high level of care for residents.

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Represented Mid-Atlantic Health Care in Baltimore in a \$75 million acquisition of five Philadelphia nursing homes.

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Completed the \$31.5 million acquisition of the Commonwealth Corporate Center, an office park situated on four contiguous properties comprising more than 80 acres in Horsham, Pa., from Advanta Corp. for our client, Centocor, Inc., a subsidiary of Johnson & Johnson.

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Completed a \$40 million transaction for our client, Blue Cross of Northeastern Pennsylvania, in the sale of a 40 percent interest in its two operating subsidiaries.

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Represented a group of actively practicing physicians/minority owners in connection with their interests in the sale of Kremer Laser Eye Centers to a public company, TLC Vision Corporation. Our clients were only selling a portion of their stock and chose to invest in the successor company.

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Represented a client in an administrative proceeding involving the federal government's Retiree Drug Subsidy Program (RDSP) in which we persuaded the government to grant the client a rare exception to the filing requirement to redress the inequitable result of routine application of the program rules.

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