

Health and Life Sciences

Overview

Today's health care environment is marked by complicated and sometimes counter-intuitive laws and regulations. The 2010 health care reform legislation has further accelerated changes in the industry and its regulatory frameworks. Taft's Health and Life Sciences Practice Group provides comprehensive and innovative legal services, assisting a wide range of individual and institutional health care providers, research institutions, and pharmaceutical, medical device, and biotechnology companies in navigating this complex and changing environment.

We regularly represent hospitals and health systems (including academic medical centers), physician groups, long term care facilities, assisted living facilities, hospices, home health agencies and individual practitioners. We counsel these clients in all phases of the regulatory world, guide them through a broad range of transactions, and represent them in a variety of adversarial proceedings, as further described below.

We regularly represent growing life sciences companies at every stage of development. We provide advice on corporate structure, financing, contracts, FDA issues, sales and marketing regulation, healthcare compliance, reimbursement and coverage issues, strategic partnership agreements, supply chain agreements and consulting agreements. We additionally provide advice on technology licensing and strategy and technology-related venture arrangements, as well as patent, trademark, copyright and trade secret protection. We assist companies, universities, research institutions, incubators, and scientists in protecting, developing, and commercializing intellectual property rights in a wide range of technical areas, including medical devices, genetics, molecular biology, pharmaceuticals, bioremediation, e-commerce and software. We work with clinical investigators, hospitals, academic medical centers and life sciences companies to help navigate the bioethical and legal issues associated with data and tissue repositories, the development of products and practices to support personalized



Melvin S. Shotten

Practice Contact
(513) 357-9311
shotten@taftlaw.com



Eric M. Simon

Practice Contact
(216) 706-3908
esimon@taftlaw.com



Catherine T. Dunlay

Practice Contact
(614) 220-0236
cdunlay@taftlaw.com

medicine, organ procurement and transplantation, stem cell research and genetic engineering.

Taft's health and life sciences attorneys regularly speak to and write for industry groups, clients, and continuing education. Our attorneys are active participants and/or leaders in the American Health Lawyers Association (AHLA) and other health care industry organizations such as Healthcare Financial Management Association (HFMA). Taft has been included in the AHLA 2011 law firm honor roll in recognition of its participation.

HONORS

Taft is ranked #1 in Cincinnati for health care law and six of the firm's attorneys located throughout Ohio and in Indiana are recognized as Best Lawyers in Health Care Law in the 2011 edition of *The Best Lawyers in America*. In addition, Taft's Health & Life Sciences Group has been honored by *U.S. News Media Group* and *Best Lawyers* as a Tier 1 practice in Cincinnati, Cleveland and Columbus and Tier 2 in Indianapolis.

REPRESENTATIVE LEGAL SERVICES

We provide our health care provider and life science business clients with sophisticated advice and services, manifesting experience in many diverse areas, including:

Transactions

- Hospital-physician joint ventures
- Mergers, acquisitions, sales, consolidations and joint ventures
- Provider affiliation negotiations, structuring and documentation
- Establishing new hospitals and health care facilities
- Establishing ancillary businesses for physician practices
- Health care facility lease and management arrangements
- Borrower and lender representation in the financing (and re-financing) of healthcare facility acquisitions
- HUD reporting compliance
- Restructuring and corporate organizational matters
- Non-compete agreements
- Ownership and succession issues
- Licensing and sub-licensing (in/out)



Timothy P. Nagy

Practice Contact
(614) 220-0220
nagy@taftlaw.com



Dave C. Bromund

Practice Contact
(317) 713-3462
dbromund@taftlaw.com

- Manufacturing/supply agreements

Health Care Operations

- Physician employment and compensation
- Ambulatory surgical centers and specialty hospitals (development, organizational and compliance issues)
 - Medical Staff and credentialing issues, including peer review
 - Medical Staff Bylaws, rules and regulations
 - Governance - tax-exempt organizations, public entities, and closely held entities such as physician practices
 - Conflicts of interest
 - Health information technology, E-prescribing and electronic medical records, including EMR donation programs
 - Clinical co-management agreements
 - Call coverage agreements
 - Hospital-based physician contracts
 - Hospital purchasing contracts
 - Clinical trial/study contracts
 - Managed care contracting, including Medicare Part D and PBM contracting
 - Preparation, review and negotiation of a wide range of contracts

Regulatory Compliance

- State licensure
- Change of ownership
- Certificates of Need
- Corporate compliance plans, audits and monitoring
- Fraud and abuse, Anti-Kickback and Stark Law compliance, including internal audits and self-disclosures
- Billing compliance
- EMTALA (Emergency Medical Treatment and Active Labor Act)
- HIPAA, HITECH and other patient privacy and security regulations
- Medical research issues, including clinical trials, human subject protections, and compliance with other FDA and HHS regulations

- Meaningful Use
- Provider-based status and under arrangements requirements
- Medicare and Medicaid enrollment and reimbursement
- Nursing home licensure/regulation
- Health care reform

Adversary Proceedings

- Administrative proceedings and appeals
- False Claims Act litigation, including qui tam actions
- Commercial and business litigation
- Alternative dispute resolution
- Medical research proceedings, including FDA enforcement actions (defense of sponsors, investigators and IRBs)
- Medical Staff fair hearings
- Medicare and Medicaid appeals
- White collar criminal defense
- Payer disputes, settlements and litigation
- E-discovery

Additional Services

- Antitrust
- Bankruptcies and Work-outs
- Construction
- Corporate Due Diligence for M&A Transactions
- Finance
- Government Relations
- Health Care Benefits Consulting, including ERISA, COBRA, HIPAA
- Labor and Employment
- Patent, Trademark, Copyright and Trade Secret Protection
- Real Estate Transactions
- Software and Intellectual Property
- Tax, Tax-Exemption, and Finance
- Technology Licensing and Strategy

- White Collar Criminal Defense

REPRESENTATIVE HEALTH AND LIFE SCIENCES CLIENTS

Healthcare Institution Clients

- Two major hospitals specializing in pediatric care
- Large health systems throughout Ohio and Indiana
- Academic medical centers
- Community hospitals
- Physician-owned specialty hospitals
- Ambulatory surgery centers - both physician-owned and hospital/physician joint ventures
- Diagnostic facilities
- Nursing facilities throughout the Midwest
- Senior living and assisted living facilities
- Home health agencies
- Hospices

Physician Groups

- Over 150 private practices spread across multiple states in a variety of specialties and subspecialties
- A number of hospital-affiliated physician organizations
- NCQA recognized medical homes
- Physician-hospital organizations
- IPAs

Life Science Clients

- Biotechnology companies
- Organ procurement organizations
- Device manufacturers
- In vitro diagnostics manufacturers
- Drug development companies
- Specialty pharmaceutical companies

Other Health Care Industry Clients

- Pharmacies (institutional, retail and independent)
- DMEPOS manufacturers and suppliers
- Free clinics
- Practice management companies
- Rural health clinics
- Federally qualified health care centers
- Health education providers
- Outpatient mental health and "day hospital" providers
- Substance abuse treatment and prevention providers
- Healthcare IT providers
- Pharmaceutical support companies
- Cosmetic manufacturers

Associations and Collaboratives

- Hospital collaboratives
- Medical associations
- Health care foundations
- Group purchasing organizations