FOLEY & LARDNER LLP

Monica R. Chmielewski

Partner

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Monica R. Chmielewski is a health care and life sciences lawyer solely focused on the representation of health care providers, pharmaceutical, biotech and medical device companies, and pharmacies in life sciences law, health care, health care transactions, clinical research, supply chain, and food and drug law. She has experience assisting clients with regards to all aspects of medical research, development and commercialization, including regarding the regulation and conduct of clinical trials and decentralized clinical trials, FDA submissions and pharmaceutical and medical device manufacturing, licensing and commercialization assistance. She is a partner and vice chair of the firm's Health Care Practice Group.

Representative Experience

Regulatory Compliance, Clinical Research, and Supply Chain

Monica provides daily counsel to numerous health systems, hospitals, academic medical centers, pharmacies and biotech, pharmaceutical and medical device companies. As such, she regularly assists clients with the following issues:

- Regulatory compliance governing all aspects of clinical research
- Investigations of research misconduct
- Institutional Review Board (IRB) issues
- The conduct of U.S. and international clinical trials
- Research grants and funding
- Government investigations and audits
- Pharmaceutical product promotion (including counsel on off-label promotion)
- 510K applications
- The regulation of software as a medical device
- Mobile medical applications
- Continuing Medical Education (CME)

- Preparation of research contracts
- Grant contracts and administration
- Pharmacy Benefit Managers (PBM) matters
- Good clinical practice (GCP) issues
- Customs import and export issues
- Hospital and physician issues
- Supply chain matters (including formation of and contracting with group purchasing organizations)
- Corporate practice of medicine and dentistry prohibitions
- Joint venture and other collaborative efforts
- Preparation and review of hospital
- Physician and other provider contracts
- Accountable care organization (ACO) formation and operation
- HIPAA
- Physician recruitment
- Corporate compliance issues
- Medical staff and peer review
- Accreditation matters
- Supply chain and procurement issues

She also has participated as transactional counsel in numerous health care, life science, and corporate transactions, including the merger, purchase and sale, or transfer of sponsorship of hospitals, pharmacies, contract research organizations (CROs), physician-owned surgery centers, health systems, home health agencies, hospices and physician practices; and the formation of ancillary services joint ventures; and counsels investors (venture capital and private equity) in investments, acquisitions, and sales.

Monica has in-depth knowledge of federal and state regulation of the drug and device supply chain, pharmacies, and laboratories. She advises entities (industry), health care providers, investors, and lenders on transactional matters and regulatory compliance, including mergers and acquisitions, recapitalizations, buyouts, restructurings, joint ventures, and broad range of commercial transactions.

Monica provides daily counsel on supply chain and materials management issues, and counsels on group purchasing organization (GPO) negotiations and formation. She also counsels health plans in their procurement of and contracting with PBMs for mail, retail, and specialty drug services in connection with commercial and government health care programs. In addition, she provides counsel regarding PBM audits, as well as on regulatory issues for various retail and specialty pharmacies, including state Boards of Pharmacy inspection and adverse findings, compounding pharmacy matters, and licensure among others.

Compliance

Monica counsels health care entities, pharmaceutical and medical device companies, pharmacies and laboratories regarding the operation and functions of their corporate compliance and integrity programs,

including assisting with the composition and development of programs; reviewing and assessing existing program effectiveness; providing compliance education and training of personnel, executive management and board members; coordinating internal investigations of compliance related concerns; and recommending any needed corrective action. She has counseled, in both in-house and outside counsel roles, individual hospitals, health systems, hospices, skilled nursing facilities, and pharmaceutical companies on matters of corporate compliance.

Telemedicine

"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)

Monica advises a number of clients, including hospitals, health systems and physician groups on regulatory and compliance issues presented by telemedicine and telehealth. Her counsel includes, but is not limited to, structuring, and negotiating professional services agreements for telemedicine services and composing telemedicine policies and procures.

Fraud and Abuse, False Claim Act, and Health Care Fraud Investigations

Monica's experience includes particular compliance issues arising under the False Claims Act (FCA), Stark Law, Anti-Kickback Statute, EMTALA, Civil Monetary Penalties Law, licensure/certification, and HIPAA. Monica works with providers on properly responding to governmental and accreditation audits and more formal investigations as well as directly with provider compliance officers and general counsel to advise them on the latest legal and Office of Inspector General requirements and standards.

Awards and Recognition

- *Chambers USA: America's Leading Business Lawyers*, Healthcare: Pharmaceutical/Medical Products Regulatory (2020-2025)
- *The Legal 500,* Life Sciences (2014)
- Named a Thomson Reuters Stand-out Lawyer (2023-2024)

Presentations and Publications

- Co-author, "GLP-1 Receptor Agonists: Clinical Trial Considerations," *Health Care Law Today* (July 22, 2025)
- Co-author, "Texas Court Vacates FDA's Laboratory Developed Test (LDT) Final Rule," *Health Care Law Today* (April 2, 2025)
- Co-author, "FDA & OHRP Draft Guidance: Including Tissue Biopsies in Clinical Trials," *Health Care Law Today* (February 3, 2025)
- Co-author, "FDA Clinical Investigations: New Guidance on Electronic Systems," *Health Care Law Today* (November 20, 2024)

- Co-author, “Cancer Drugs: Clinical Trial Issues for Antibody Drug Conjugates (ADCs)/Antibody Therapeutics,” *Health Care Law Today* (November 5, 2024)
- Speaker, “Medical Research Misconduct Proceedings: New HHS-ORI Final Rule; Key Procedural Reforms and Requirements,“ Strafford Webinar (December 4, 2024)
- Co-author, “Decentralized Clinical Trials: Research Misconduct Risks & How to Avoid Them,” *Health Care Law Today* (September 30, 2024)
- Speaker, “Examine the Recent FDA Guidance Surrounding Digital Health Technologies,“ 5th Clinical Trial Agreements (August 22, 2024)
- Co-author, “Clinical Trials: FDA Publishes Draft Guidance on Diversity Action Plans,” *Health Care Law Today* (July 25, 2024)

Sectors

- Health Care & Life Sciences
- Manufacturing
- Medical Devices
- Pharmaceuticals
- Supply Chain

Practice Areas

- Corporate
- Health Care
- Health Care Transactions

Education

- Wayne State University (J.D., cum laude)
    - Order of the Coif
- Franklin and Marshall College (Government and Ancient History and Archeology)

Admissions

- Illinois
- Michigan