



DAVID W. OHLWEIN

Nashville Office

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David has extensive experience in healthcare regulatory contracting and transactions matters, including: life science company transactions and providing counsel on the federal Anti-kickback statute (AKS), False Claims Act (FCA), HIPAA, Stark Act, and FDA compliance.

PRACTICE AREAS AND INDUSTRY TEAMS

- Health Law
- Pharmaceutical, Medical Device & Healthcare Industry Team

EXPERIENCE

- Lead counsel in wide variety of commercial transactions for \$3.5 billion division of medical device company, including research, product development, consulting, purchase; supply; distribution, sales, mergers, acquisitions and divestitures; product development and manufacturing agreements.
- Extensive experience providing counsel on compliance with applicable healthcare laws and regulations, including the federal Anti-kickback statute (AKS), False Claims Act (FCA), HIPAA, and Stark Act.
- Significant experience providing counsel and advice to marketing, quality, sales, and operations to ensure compliance with applicable FDA laws, regulations and guidance documents.
- Extensive experience providing counsel and advice in security services and food manufacturing industries including wide variety of commercial transactions, OSHA/EPA program implementation and auditing, labor/employment, food safety and USDA compliance, and corporate governance.

BAR ADMISSIONS

- Tennessee, 2003
- Illinois, 1990 (*Inactive*)

DISTINCTIONS

- Senior Legal Director, Medtronic Spinal & Biologics
- Assistant General Counsel, Guardsmark, LLC
- Assistant General Counsel, OSI Industries, Inc.

ASSOCIATIONS

- American Bar Association
- Tennessee Bar Association

EDUCATION & HONORS

- DePaul University, J.D., 1990
- University of Iowa, B.B.A., Finance, 1987

PAPERS, PRESENTATIONS AND PUBLICATIONS

- Author, "Recent FDA Regulatory Guidance Involving Medical Devices," *Pro Te: Solutio*, Vol. 11, No. 2, September 2018.
- Author, "Off-Label Use: Protected Commercial Speech or Misbranding?" *Pro Te Solutio*, Vol. 8, No. 5, Spring 2016.