

Representative Projects in Conflicts of Interest

- Counsel to the special committee formed by the board of The Cleveland Clinic Foundation to conduct an internal review of potential conflicts of interest arising from financial relationships between medical device manufacturers and members of its executive management team and its board of directors. Assisted in the development of a comprehensive, multi-disciplinary conflicts of interest compliance infrastructure in governance, research and clinical care matters.
- Counsel to the board of University of Pittsburgh Medical Center in all aspects of the development and implementation of a “best in class” comprehensive conflicts of interest compliance program. The project encompassed individual and institutional conflicts compliance in the context of all key areas (governance, clinical care, research, technology transfer and other invention commercialization initiatives, purchasing, and fundraising). It also encompassed revisions to board committee structures, development of policies, procedures, guidelines and tools, and establishment of a centralized database of interests across all functional lines, for use in identifying, assessing and managing conflicts of interest. Coordinated these efforts with the conflicts program of the affiliated University and the University’s adoption and implementation of a general policy on financial relationships with vendors.
- Assist a nationally recognized specialty hospital and research institute in developing a compliance infrastructure to address potential institutional conflicts arising from various aspects of its operations that could have implications for research and clinical care. The operational areas encompassed included those of an affiliated entity formed to form strategic partnerships and other spin-offs as a means of commercializing early stage technology developed internally.
- Reviewed and upgraded a health system’s overall conflicts of interest in research program.
- Reviewed and upgraded an academic medical center’s policies and procedures for addressing individual conflicts of interest in research.
- Conducted a research conflicts of interest internal investigation for a freestanding research institute. Recommended corresponding remediation steps.
- Assisted a major developer, manufacture and marketer of consumer and professional medical diagnostic products with the review of documents related to conflicts of interest following a subpoena.
- Designed and conducted a conflicts of interest symposium for the leading scientists and senior management of a nationally-recognized specialty hospital and research institute.
- Developed compliance policies for both institutional providers and for healthcare product vendors relating to relationships and interactions between such vendors and their personnel and institutions and their personnel and professional staffs. Such policies were designed to address the full scope of compliance issues arising from such relationships and interactions, fraud and abuse, off-label use promotion, and research and clinical care conflicts of interest.

- Revised policies and procedures relating to formulary committees to include specific provisions for maintaining the independence of, and preventing conflicts of interest among, the committees' members. Established similar policies and procedures for new committees being formed to review and approve medical devices and other medical technology for use within an institution.
- Designed and conducted an all-day compliance training program for sales executives, in-house legal counsel and compliance officers of major medical device vendors and distributors. The program focused on the full scope of legal and regulatory issues arising from relationships and interactions between such vendors and their personnel and institutions and their personnel and professional staffs. It also featured mock illustrations of how commonplace behaviors can lead to civil and criminal enforcement investigations, grand jury involvement, and other prosecutorial initiatives.
- Advised major life sciences company on conflict management strategies for potential conflict arising from funding of secondary research studies emanating from sponsored primary research studies.

CONTACTS

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