

Drugs and Medical Devices

HLB serves the needs of those who bring advances in medication and medical devices to market and improve the health and lives of countless patients. We work closely with clients in the drug and medical device sector to facilitate their work, protect their interests and innovations, and position them for successful transactions that maximize the value they receive from their efforts while minimizing compliance concerns.

Our attorneys have a wealth of specialized experience helping pharmaceutical and device manufacturers, distributors and wholesalers, pharmacies, hospitals, physician groups (including physician-owned distributorships), and investors develop and commercialize drug and device innovations.

Our comprehensive understanding of the law and business of health care helps clients navigate complicated regulatory requirements and supports beneficial transactions and commercial relationships. We recognize how critical it is to structure these transactions and relationships to comply with complex laws and regulations and avoid raising red flags for regulators. As nationally recognized fraud and abuse experts in areas such as the Stark Law, federal and state anti-kickback statutes, the False Claims Act, and other fraud and abuse laws and regulations, HLB regularly counsels clients on complying with regulatory requirements and defends them in federal and state investigations and enforcement actions. We also help clients navigate the legal issues involved in clinical trials and the crafting of joint venture, research, licensing, and vendor agreements.

HLB's regulatory capabilities for our drug and device clients are anchored by attorneys who focus their practices on proactive compliance and productive interactions with government regulators, investigators, and attorneys. We leverage our institutional knowledge and the insights of lawyers with extensive government-side experience to favorably resolve investigations, enforcement actions, and other disputes. HLB also has an industry-leading Medicare practice, which helps our clients with Medicare enrollment, compliance with coverage standards, and pricing, billing, and payment issues.

The significant amounts of data, PHI, and proprietary information involved in product development and testing have substantial value but also raise potential patient privacy and HIPAA concerns. HLB combines our robust health information privacy and security practice with experienced business counsel to protect our clients from both regulatory and competitive threats.

On legislative and policy matters, HLB's active and respected presence on Capitol Hill and throughout the Executive Branch helps facilitate positive change and a favorable policy environment for our drug and device clients.