

## FDA & LIFE SCIENCES

Hall Render attorneys have experience advising clients in various areas of pharmaceutical, medical device, biotechnology and life sciences research law. We have handled a broad spectrum of matters for our clients, including regulatory compliance, governmental investigations and defense, conducting clinical trials, product liability defense, intellectual property, labor and employment and business transactions. Our experience in the many areas of law impacting the life sciences industry allows us to provide prompt, effective counsel to our clients. We have also assisted clients with related areas, such as advertising medical products and pharmaceutical trade.

### AREAS OF FOCUS

- Administrative Matters
- Advice on health care products advertising
- Advice on the marketing and distribution of pharmaceutical products
- Advice on trade/sale of pharmaceutical products
- Advice regarding intellectual property and technology transfer issues for pharmaceutical products and medical devices
- Assistance with regulatory inspections and corrective action responses
- Clinical Research
- Clinical Trial Agreements
- Compliance
- Counsel regarding pricing issues
- Creation, organization and improvement of research programs
- Data transfer and privacy issues
- Facilitation of effective communications with agencies, authorities and legislative bodies
- False Claims Act counsel
- Federal and state anti-kickback and fraud and abuse laws
- Federal and state self-referral laws, including the federal Stark law
- Federal, state and international privacy laws, including HIPAA and the EU Privacy Directives
- Food and Drug Administration regulations
- Good clinical practice methods
- Governmental Regulation
- Institutional Review Board issues
- Intellectual Property and Technology
- Intellectual property and technology transfer
- Legal monitoring of the development of new pharmaceutical products and medical devices
- Licensing
- Pharmaceuticals and Medical Devices
- Preserving integrity in research
- Research Misconduct Investigations
- The Common Rule