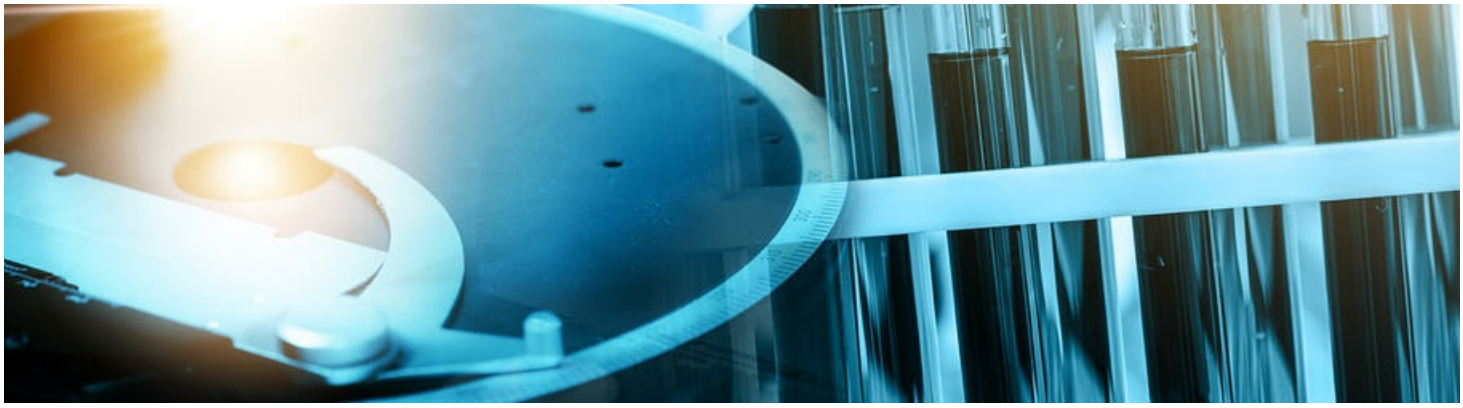
McElroy Deutsch

Pharmaceutical, Medical Devices & Life Sciences



The experienced pharmaceutical lawyers and medical device attorneys at McElroy Deutsch regularly represent pharmaceutical and medical device manufacturers, clinical research organizations (“CROs”) and other life sciences companies. These companies range in size from small start-ups to publicly traded multinational corporations and include manufacturers of brand name and generic drugs, as well as those developing new chemical entities (“NCEs”).

Our law firm's scope of expertise includes consulting on and preparing Master Services Agreements, Clinical and Analytical Study Agreements, Clinical Site Agreements, Project Agreements, Intellectual Property Agreements, and the like. McElroy Deutsch has assisted companies in all phases of their clinical studies, including discovery, preclinical, toxicology and Phases I, II, and III. Our pharmaceutical lawyers also have counseled clients on the regulatory and liability aspects of clinical pharmacology units (“CPUs”), including issues of state licensure, retention of physician investigators, procedures and requirements of sponsors governing the use of investigational new drugs, development and review of investigative review board (“IRB”) protocols, as well as issues of privacy, confidentiality and informed consent in connection with the use of human subjects.

Our law firm's representation of CROs has been national in scope and includes litigation and consultation concerning actions arising from alleged breach of study agreement, breach of protocols, standard operating procedures and industry practices, as well as other study-related FDA issues. Our attorneys also have provided representation on issues arising from improper billing practices, antitrust allegations, wholesale pricing of drugs and workplace discrimination.

Our pharmaceutical lawyers have conducted seminars for and offered counseling to pharmaceutical companies relating to drug liability trends in the United States, the prevention and detection of Medicare fraud and abuse issues, compliance with the federal anti-kickback statute and false claims act, sales and marketing guidelines promulgated by the Office of Inspector General, and internal safeguards for pharmaceutical billing/pricing practices. Our attorneys also have assisted our pharmaceutical and life sciences clients with issues involving the Medicare Part D prescription drug coverage program, the Medicaid drug rebate program, and the 340B drug pricing program, as well as the review, development and implementation of corporate compliance programs, and

environmental, health and safety policies and guidance for their manufacturing plants.

Working closely with each client, such as Johnson & Johnson, the attorneys in our Labor and Employment Practice have provided a full range of labor and employment counseling, including collective bargaining negotiations, and the development of policies and procedures and guidance on the Family Medical Leave Act (FMLA), the New Jersey Family Leave Act (FLA), the Americans with Disabilities Act (ADA), the New Jersey Law Against Discrimination (LAD), and the New Jersey Conscientious Employee Protection Act (CEPA). Our law firm has extensive experience counseling management on reductions in force and other company restructurings, including selection processes, Worker Adjustment and Retraining Notification (WARN) Act, disparate impact, severance and Older Workers Benefit Protection Act (OWBPA) issues. We have conducted numerous employee interviews and internal company investigations, and have developed and implemented training and education programs for our clients' officers, directors, management, supervisors and front-line employees covering such topics as interview strategies, effective discipline and discharge practices, leave of absence rights, wage and hour practices, and the proper handling of sexual harassment and discrimination claims.

In addition, McElroy Deutsch attorneys serve as both lead counsel and approved outside counsel for pharmaceutical companies such as Abbott Laboratories, Bayer Corporation, Knoll Pharmaceutical Company, and Sanofi-Sythelabo in litigation involving claims of personal injury and wrongful death due to alleged defective pharmaceutical products. Our lawyers have also served as lead counsel in the Baycol and Phenylpropanolamine certified mass-tort litigations in New Jersey and have defended Aventis Pharmaceuticals in contaminated polio vaccine (SV40 virus) cases.

Our attorneys, a number of whom are former federal, state and county prosecutors, have represented national and international corporations, American and foreign nationals, executives, and professionals in a vast array of criminal matters and other governmental investigations at the local, state and federal levels. We have achieved successful results for our clients in matters involving alleged health care fraud and abuse, violations of food and drug, environmental, tax, campaign finance, ERISA, labor relations, RICO, trade secrets, and banking laws, as well as bribery, false claims, public corruption, perjury, false statements, obstruction of justice, money laundering, mail and wire fraud, and conspiracy. Our lawyers also have successfully negotiated Deferred Prosecution Agreements for our clients.

View a list of our pharmaceutical, medical device & life sciences lawyers.

Related Practices

Corporate Transactions

Health Care

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Intellectual Property

Labor & Employment

Litigation

Product Liability

Securities

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