

OUR PRACTICE

Drug, Device and Life Sciences

The attorneys in Baker Donelson's Health Law Department have extensive experience helping clients in the pharmaceutical, medical device and biomedical industries keep abreast of the rapidly changing regulatory and business environments in which drug, device and life science companies operate. We know both the law and the business, providing counsel to hospitals, pharmacies, wholesalers, medical device companies, durable medical equipment (DME) and supply companies, pharmaceutical companies and life science companies.

When disputes arise, we work to resolve them through the litigation process and alternative dispute resolution methods, such as mediation and arbitration. We handle a wide array of cases, including product liability suits, commercial disputes, antitrust cases, labor and employment problems, and regulatory and governmental matters. Our trial lawyers participate in industry trade groups and actively monitor developments in litigation targeting the drug, device and life science industry. Our litigation defense experience allows us to proactively identify the most dangerous cases and conclude them on terms most advantageous to our clients.

From company formation to product launch, regulatory guidance and courtroom advocacy should problems arise, we provide a full range of legal services to the industry.

Product Launch

Launching a drug or medical device is an extraordinarily complicated process, requiring a company to navigate through a labyrinth of laws and Food and Drug Administration (FDA) regulations as it conducts clinical trials, assures control of intellectual property and negotiates vendor agreements. We have experience with almost every facet of this often lengthy and difficult process, including:

- Drafting joint venture, research and licensing agreements by and among health care institutions, medical researchers and manufacturers;
- Guiding clients on the numerous legal issues that arise when conducting clinical trials (Phases I-IV) and negotiating vendor relationships;
- Securing pre-market approval of pharmaceuticals and medical devices from the FDA;
- Reviewing marketing information, promotional material and product labeling to assure compliance with FDA regulations and guidance; and
- Developing regulatory training and compliance programs, including educational materials, for sales and marketing staff.

Commercialization

With our powerful combination of health care law and business experience, Baker Donelson attorneys provide strategic advice and regulatory guidance to clients as they move drug, device and life science products to markets around the world. We regularly advise clients on business structure and formation, commercialization, labor and employment, regulatory compliance, tax, real estate and public policy matters.

Many of our attorneys have served as in-house counsel or in federal agencies, including Health and Human Services, the Centers for Medicare and Medicaid Services, FDA, Federal Trade Commission, Patent and Trademark Office and Drug Enforcement Administration. As a result, we understand both the nuances of a

company's contractual, regulatory and operational needs and how to balance those needs so the company complies with the law yet remains flexible and competitive.

Transactions

With attorneys experienced in both transactional and industry issues, we provide tailored, regulatory and legal assistance to life sciences companies in all types of transactions. We handle initial public offerings and private placements of debt and equity securities; visit sites and perform due diligence reviews for potential acquisitions and strategic partnerships; and regularly advise purchasers on the regulatory risks associated with proposed acquisitions, including fraud and abuse issues related to DME joint ventures. Our combination of knowledge and experience allows us to provide legal assistance for innovative arrangements, such as a biotechnology/life sciences fund established jointly by a major academic medical center and a NYSE company.

Product Liability

Our trial attorneys have defended numerous medical product liability cases for manufacturers, distributors and retailers, including lawsuits with plaintiffs from around the world and class action lawsuits with hundreds of millions of dollars at stake. We have defended companies in suits alleging the defective design and manufacture of products such as dialysis equipment, orthopedic devices, cardiac defibrillators, spinal screws, birth control devices, hormone replacement therapy, intravenous equipment, anesthesia pumps, blood products, mechanical heart valves, breast implants, acne drugs and anti-nausea medications, among many others.

In addition to handling single plaintiff cases, we have served as national and regional coordinating counsel in product liability cases. We have also managed the defense of large class action, multiple-suit and mass tort litigation, including consolidated multi-district proceedings. Some have involved hundreds or even thousands of plaintiffs, with products marketed and distributed worldwide.

Business

Pharmaceutical, medical device and life science companies confront the same types of commercial disputes as other businesses. Our litigators' deep knowledge of these industries, gained through our business, regulatory and product liability experience, enables us to fully appreciate our clients' specific dispute resolution goals and concerns. Our teams provide a full spectrum of services, including work on commercial, intellectual property and contract disputes, antitrust actions, regulatory counseling and assistance with government investigations.

Baker Donelson's attorneys have served as outside patent counsel for a number of pharmaceutical, medical device and life science companies, handling patent infringement cases both in the U.S. and internationally in venues such as the International Trade Commission. We have represented pharmaceutical manufacturers in average wholesale price (AWP) litigation and facility and product licensing. Our appellate attorneys were even responsible for establishing the learned intermediary doctrine in Alabama.

Regulatory Matters and Government Investigations

Baker Donelson's attorneys have extensive experience handling the myriad, complex regulatory issues that drug, device and life science companies confront on a daily basis. Our services include:

- Assisting with coverage, payment and coding issues for new product launches.
- Reviewing, developing and implementing compliance programs.

- Helping clients respond to FDA warning letters and deficiency notices, including the determination of corrective actions.
- Self-reporting potential overpayments involving average wholesale price issues to CMS and the Office of Inspector General (OIG).
- Advising clients on product recalls and handling of adverse events.
- Restructuring operations to comply with developments in the Anti-Kickback Statute.
- Working with the National Clearinghouse and each regional Durable Medical Equipment Regional Carrier (DMERC) to facilitate Medicare enrollment.
- Reviewing compliance with Medicare coverage standards and medical record reviews to support claims billed to Medicare and secondary payers.



Representative Matters

- Lead Counsel for the world's largest manufacturer of store-brand over-the-counter drugs in all phenylpropanolamine (PPA) litigation in Tennessee.
- Led a team of more than 50 attorneys and legal professionals in defending a pharmaceutical company in diet drug litigation in Tennessee, consisting of more than 2,500 federal court cases throughout the state. Also served on the client's national expert witness team deposing medical causation experts throughout the country.
- Won dismissal in federal court for a global medical device company based on preemption of plaintiffs' tort claims.
- Obtained summary judgment on behalf of a medical device manufacturer against claims that it negligently manufactured and sold dialysis products, thereby saving the company several hundred thousand dollars.
- Represented a multi-national biomedical science company in lease review.
- Represented an over-the-counter product manufacturer in a consumer protection action brought by the Mississippi Attorney General alleging the company engaged in false and deceptive labeling.
- Represented a manufacturer of opioids in actions brought by the Mississippi Attorney General, political subdivisions, and hospitals alleging over-promotion.
- Represented a major hospital system in a pharmaceutical *qui tam* matter.
- Served as lead counsel for the distributor of anesthesia medication in more than 250 cases involving more than 4,000 plaintiffs in Las Vegas, Nevada.
- Served as lead counsel for a homeopathic drug manufacturer in a California putative class action alleging false drug labeling.
- Obtained summary judgment for a medical device manufacturer in a products liability case relating to an alleged defect in a pain management pump.
- Defended a major manufacturer of pelvic mesh devices in multiple suits in federal court, and also served on the client's national expert witness team.
- Obtained summary judgment for a prosthetic device assembler and seller in a federal court products liability suit alleging injury from the failed device.
- Represented a biopharmaceutical drug company in connection with a \$15 million follow-on offering.
- Vast experience as national and regional counsel in pharmaceutical product defect cases, including lead counsel for distributor in mass tort propofol cases in Las Vegas, lead counsel for manufacturer/distributor in Phenergan cases filed throughout the US, and lead counsel for largest generic manufacturer of store-brand products in all phenylpropanolamine (PPA) cases filed in Tennessee.