

# OUR PRACTICE

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## Specialty Pharmacies and Pharmaceuticals

**Advances in drug development technology have given rise to a new and rapidly growing category of pharmaceuticals designed to treat chronic diseases such as rheumatoid arthritis and multiple sclerosis as well as rare genetic conditions like hemophilia. For manufacturers, delivering such drugs to patients is a complex challenge. Many require refrigeration; they are often delivered by mail; and many are injected or infused, presenting a challenge to patients. They are also expensive.**

These medicines have, in turn, given rise to the specialty pharmacy, designed to meet the legal, regulatory and logistical challenges of delivering such drugs to patients – and of helping patients use them safely.

Baker Donelson has a national practice providing all types of legal guidance to specialty pharmaceutical and rare disease clients, including small and large manufacturers, pharmacies, wholesalers, distributors, group purchasing organizations, reimbursement hubs, benefit managers and entities covered by the federal 340B drug discount program. Led by the former chief counsel of the nation's largest specialty pharmacy, our team has a comprehensive understanding of the legal and business needs of companies working throughout the supply chain. We have negotiated hundreds of contracts, including wholesale distribution, direct distribution and fee-for-service agreements. We've worked on software design agreements and with firms that provide reimbursement hub services, co-pay and coupon program services, adverse event services and clinical hotline services.

Baker Donelson's attorneys have handled an extraordinary number of pharmaceutical transactions, including sales and acquisitions of manufacturers, pharmacies and service companies. Our knowledge of the specialty pharmaceutical business as well as the law is especially valuable to manufacturers as they navigate the challenging process of launching a new product. We have experience helping with all aspects of a launch, including:

- Drafting distribution agreements;
- Structuring compliant service and data agreements;
- Implementing Risk Evaluation and Mitigation Strategy (REMS) programs, including Elements to Assure Safe Use (ETASUs) and patient registries;
- Establishing freestanding service arrangements for the provision of clinical call centers, site-of-care solutions and clinical liaison programs;
- Working with third-party logistics companies and wholesalers to establish effective distribution networks and establish 340B and VHA chargeback structures; and
- Negotiating contract sales force or co-branding agreements.

Given the high cost of most specialty pharmaceuticals – a significant amount of which is often borne by patients – reimbursement is a particularly important consideration. Our lawyers have extensive experience in this arena, too, including negotiating and implementing rebate agreements with health plans and Pharmacy Benefit Managers (PBMs); obtaining Prescription Drug List (PDL) and Pharmacy and Therapeutics (P&T) coverage for newly launched products; analyzing the reimbursement and payment implications of different distribution channels; and structuring and negotiating arrangements with reimbursement hubs and patient assistance programs.



## Representative Matters

- Provided a successful defense in nurse and pharmacy malpractice cases.
- Obtained summary judgment for a pharmaceutical manufacturer in multiple products liability cases involving its co-promotion of prescription pain medication.
- Obtained summary judgment for a pharmaceutical manufacturer in a dispute with a former sales representative relating to the company's performance incentive plan.
- Served as government contracts counsel for the negotiation of an asset sale on behalf of two sister pharmaceutical companies. The purchaser was a buyer affiliated with and funded by a Chinese entity. Assets sold consisted of realty and personalty in Kentucky and Puerto Rico, and purchase price, including tax credits and earnouts, exceeded \$36 million. Representation involved the assignment of contracts with state and federal government agencies, the negotiation of a novation agreement and other assignment agreements, and other regulatory and compliance matters.