FRIER LEVITT
ATTORNEYS AT LAW

Pharmaceutical and Biologics Manufacturer *Services*

Litigation | Compliance Regulatory Counseling Services at Every Stage of Product Development

Frier Levitt provides a wide range of services to pharmaceutical and biotech companies, assisting them in controlling the narrative on drug pricing, understanding the maze of existing and newly enacted state and federal laws and regulations, and developing comprehensive strategies to deal with the ever-evolving prescription drug channel, including Pharmacy Benefit Managers (PBMs) policies.

Frier Levitt attorneys have a wealth of experience navigating the ever-changing landscape of the life sciences industry. Legal services provided include:

Consultation on Drug Channel and PBM Industry

Understanding the relationships between and among the different stakeholders in the drug supply channel is key to being successful in any commercialization strategy. Among the most critical for pharmaceutical and biotech companies to follow is the relationship between PBMs and pharmacies, who carry and dispense manufacturers' products. These relationships are defined largely by lengthy and onerous participation agreements and provider manuals between PBMs and network pharmacies. However, these relations are being increasingly regulated by state and federal law, including "any willing provider" laws.

Frier Levitt routinely counsels market access, managed care and reimbursement support professionals within pharmaceutical companies on PBM industry trends, including, drug pricing, DIR fees, the 340B program, vertical integration and restrictive payor networks, and the impact on different stakeholders. We provide this important industry insight from the perspective of having represented pharmacies, dispensing physicians, wholesale distributors, and manufacturers, allowing the pharmaceutical and biotech industry to make informed and comprehensive business decisions.

Drug Pricing and Price Reporting Compliance

Pharmaceutical and biotech manufacturers face a litany of business and compliance concerns related to drug pricing. Manufacturers have faced growing scrutiny when it comes to establishing drug prices – not only from lawmakers and regulators, but also from payors and patients alike. Frier Levitt understands the federal and state laws on drug pricing and reimbursement and can help develop sound pricing strategies.

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Frier Levitt routinely guides clients on price reporting compliance, including “AMP” and “Best Price” calculation and reporting. In an industry that has become more and more vertically integrated, the lines separating customers become blurred, and it is critical to develop compliance reporting policies.

Frier Levitt recognizes the growing challenges manufacturers face with respect to 340B compliance, as well as new and novel opportunities. We can help you stay abreast of the latest legal developments with respect to the 340B program and explore new avenues and policies.

Pharmacy Benefit Manager (PBM) and Regulatory Scrutiny of Relationships Between Drug Manufacturers and Pharmacies

PBMs have broadened their scrutiny of pharmacy-manufacturer relationships. They are aggressively seeking out certain pharmacy-manufacturer relationships. Recently, PBMs have gone beyond publicly criticizing “captive” pharmacies, and have begun targeting manufacturer-sponsored hub arrangements, removing drugs from formulary, attacking copayment assistance programs, and scrutinizing pharmacy sales from any one manufacturer. Particular focus is additionally applied to drugs that are distributed in a Limited Distribution Drug (LDD) model that excludes PBM-owned pharmacies.

As a result of these trends, drug manufacturers need to be aware of PBM trends and PBM pharmacy network requirements. In the past, PBMs have relied on technical noncompliance with contractual requirements as a pretext for network termination, while more recent actions include pressing copay accumulator programs that reverse the effectiveness of manufacturer copayment assistance programs, decreasing reimbursement to independent pharmacies on specialty and LDDs as well as DIR fee programs. Frier Levitt assists manufacturers in dealing with these complex topics, including:

- Formation of hub arrangements and contract negotiations
- Structuring arrangements between manufacturers and marketing companies
- Negotiating and drafting supplier and distribution agreements

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Reimbursement Support and Prior Authorization Assistance

Health plans, including employer and government-sponsored health care programs, use a variety of utilization and cost management tools – such as prior authorization – to optimize patient outcomes and reduce drug spending. It is no secret that prior authorization process is complex, time consuming, and often requires coordination between multiple parties to be completed. Such a delay can hinder patient access to manufacturers' products. As a result, many pharmaceutical companies have sought to provide various forms of reimbursement support and/or prior authorization assistance, to provide tools and resources to prescribers, pharmacies and patients alike in seeking approval for their medications.

However, these activities not only must be properly structured to maintain compliance with federal and state laws (such as the Anti-Kickback Statute), but must be carried out compliantly from an operational perspective. Several recent enforcement examples have highlighted the risks to manufacturers if incorrect or misleading information is provided, or if safe harbors are not met. Moreover, many PBMs have recently adopted their own rules with respect to acceptable prior authorization practices, adding further compliance challenges. Frier Levitt routinely assists companies in structuring compliant reimbursement support programs, and ensuring that such programs are operated appropriately.

Patient Access and Affordability

Between copay coupons, contributions to charitable assistance programs, and free drug programs, manufacturers utilize a variety of methods to increase patient affordability and access. But these opportunities are not without risk. Regulators and PBMs are becoming increasingly focused on the use of these programs to provide benefits to patients and the impact they have on drug prices. Several major pharmaceutical companies have settled with the Federal government and agreed to pay millions of dollars and enter into Corporate Integrity Agreements (CIAs) over payments made to independent charitable foundations. Meanwhile, through the use of copay accumulators and other tools, PBMs have equally stepped up their scrutiny over manufacturer-sponsored assistance programs. Frier Levitt assists manufacturers in complying with CIAs, and in developing compliant patient access and assistance arrangements.

Formulary and Rebates

PBMs have a powerful influence on drug pricing. When PBMs demand rebates, manufacturers often increase the list price of drugs, causing a cycle of escalating drug costs to patients and plan sponsors. If a PBM has threatened to put your drugs on their "drug exclusion list" because you have not paid a sufficient rebate, you have rights and we can help. In addition, we help manufacturers negotiate rebate arrangements with PBMs, as well as commercialization and market access agreements. We provide advice and counseling to pharmaceutical companies on the role of Rebate Aggregators (or Rebate GPOs), who are often owned by or affiliated with PBMs, and pocket a majority of the rebate funds, sharing only a portion with the Plan Sponsors. Frier Levitt can assist your company in developing a comprehensive market access strategy.

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Value Based Contracting

Over the past several years, there has been a greater focus in healthcare to pay for value, rather than volume. As a result, opportunities exist in the form of value-based contracting, whether through innovative contracting with PBMs and payors, or through joint ventures with coalitions of providers. These models provide manufacturers the ability to help steer the narrative on drug pricing, and deliver cost savings in line with higher quality and access. Frier Levitt has addressed each of these concepts with PBMs, payors and providers alike. We can explore innovative "direct to plan" arrangements among manufacturers, providers and plans, and can assist your organization in taking advantage of recently-enacted price reporting rules providing more flexibility for value-based contracting.

Risk Evaluation and Mitigation Strategy Programs

The firm guides drug manufacturers in Risk Evaluation and Mitigation Strategy (REMS) programs, including FDA Submissions and Compliance, distribution, monitoring and auditing of REMS vendors, adverse drug event tracking, Elements to Assure Safe Use (ETASU) and Medication Guides, REMS related civil and criminal litigation, PBM related REMS counseling, and preparation of REMS patents for Orange Book listing.

HIPAA Compliance

Manufacturers often request or require prescription data from their partners and affiliates in order to evaluate marketing efforts, patient assistance programs, adherence, patient outcomes and quality metrics. Health Insurance Portability and Accountability Act (HIPAA) restricts the transmission of data in order to protect patient privacy and security, and may impose limitations on a manufacturer's ability to compile the data they seek. HIPAA violations may result in civil penalties and/or even criminal penalties, which may extend to the employees, including, but not limited to, sales representatives and executives. Frier Levitt can assist in developing compliant arrangements and data reports that provide manufacturers with the substance they require without placing affiliates in a position to breach their obligations pursuant to federal law.

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Intellectual Property (IP) legal services to protect your business and inventions. Our team can assist with:

- Patent, Trademark and Copyright registrability opinions, preparation and prosecution before the U.S Patent & Trademark Office
- Patent Infringement and Intellectual Property disputes and litigation
- Prosecution and Advocacy before the Trademark Trial and Appeal Board
- Trade Secrets
- Patent Invalidity and Freedom-to-Operate Opinions
- Strategic Due Diligence
- Patent Portfolio Management and Valuation
- Hatch Waxman matters and ANDA certifications
- BPCIA Litigation (Biosimilar patent litigation)
- Inter Partes Patent Review before the PTAB

The stakes for IP protection have never been higher. Our IP Litigation Practice provides a full range of litigation in patents, trade secrets, unfair competition, false advertising, copyrights and trademarks. We handle IP disciplines in a broad range of technologies ranging from computer software to prescription/OTC pharmaceuticals and biosimilars. We represent market leaders, start-ups, and others in-between and develop winning strategies to protect their investments both at the bargaining table and at trial.

Labeling and Advertising/Off-Label Promotion

It is well known that the U.S. Food and Drug Administration (FDA) has long taken the position that a medical device or drug manufacturer who promotes any unapproved uses of FDA-approved drugs/devices is in violation of the Federal Food, Drug, and Cosmetic Act (FDCA). The FDA has asserted that off-label promotion leads to misbranding of the product and circumvention of the regulatory approval process that is taken to ensure product safety and efficacy. Interestingly, it appears that FDA's position on off-label promotion has changed somewhat in the recent past.

On June 12, 2018, the FDA issued a statement about what was portrayed as a new effort to advance medical product communications to support drug competition and value-based healthcare. According to the statement, the FDA is now approving "truthful and non-misleading" off-label promotion when directed to an audience of third-party payors. The FDA's revised approach on this critical issue has brought positive outcomes.

Pharmaceutical and medical device manufacturers should take cautionary steps when implementing the FDA's perspective on off-label promotion in their marketing strategy. Frier Levitt can assist with evaluating the marketing and promotional materials, campaigns and training materials, and provide label evaluation. Our attorneys can provide a blue-print to the manufacturers to maximize the market access/share while minimizing the risk of potential lawsuits.