Par Pharmaceuticals

Modern medical fraud

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Executive Summary

Par Pharmaceutical, a once-prominent player in the U.S. generic drug market, has been repeatedly entangled in federal enforcement actions for egregious fraud. These cases span off-label promotion, collusion on drug pricing, and illegal kickback schemes targeting vulnerable populations. In a 2013 settlement, Par paid $45 million after promoting Megace ES to elderly nursing home patients for unapproved uses, despite known risks of severe side effects and death. Investigations revealed the company deliberately trained sales staff to push the drug to high-risk populations and hid data from federal programs. Par's misconduct extended beyond marketing abuse. From 2016 onward, Par became a key target in a sweeping DOJ antitrust probe that exposed systemic price-fixing among generic drug manufacturers. Internal communications and cooperating witnesses confirmed that Par participated in coordinated pricing agreements, suppressing competition across critical markets. Additionally, whistleblower complaints revealed a pattern of kickbacks and improper inducements throughout the 2000s, involving consulting sham contracts, free samples, and preferential rebates designed to secure product placement. These practices violated federal anti-kickback laws and misbranding statutes and underscored the company's sustained pattern of intentional fraud. Taken together, Par's conduct reflects deep-rooted corporate strategies that prioritized profit over patient safety, regulatory compliance, and market integrity.

Par Pharmaceuticals:

Founded in 1978, Par Pharmaceutical positioned itself as a major supplier of generic and specialty pharmaceuticals in the United States. Headquartered in New York, the company rapidly expanded through acquisitions and product launches, marketing a wide range of generics for hospitals, clinics, and pharmacies. It became especially known for targeting complex generics

and niche therapeutic areas with high reimbursement potential. Par's corporate trajectory changed significantly in 2012, when it was acquired by private equity firm TPG Capital in a $1.9 billion deal. Under TPG's stewardship, the company aggressively scaled its generics pipeline — a shift that coincided with many of its fraudulent marketing and pricing practices. In 2015, Par was acquired again by Endo International for $8 billion. While the Endo deal aimed to bolster both companies' portfolios, it also brought Par's legal baggage under closer scrutiny. Since then, Par has faced multiple government investigations, civil settlements, and ongoing legal challenges tied to its historical conduct.

Off-Label Promotion of Megace ES

In one of its most prominent fraud cases, Par Pharmaceutical agreed to a $45 million settlement with the U.S. Department of Justice in 2013 for unlawfully promoting its appetite stimulant Megace ES to elderly patients in nursing homes — a demographic for whom the drug was neither safe nor approved. Megace ES (megestrol acetate) was intended for AIDS patients suffering from cachexia. However, Par saw commercial opportunity in the broader elderly population and deliberately marketed the drug for this off-label use. The DOJ found that Par trained its sales representatives to promote Megace ES to elderly patients with dementia, Alzheimer's, or other chronic conditions — even though clinical data showed these patients faced a high risk of deep vein thrombosis, cardiovascular events, and death. To maximize sales, Par allegedly instructed its staff to target long-term care facilities and encouraged the use of Medicare and Medicaid to fund the prescriptions. This resulted in the submission of false claims to federal healthcare programs — a core violation of the False Claims Act. Notably, the company's own internal studies showed the drug was not safe for the elderly, but those findings were never disclosed to prescribers or regulators. Instead, Par masked risks and exaggerated

benefits, prioritizing market penetration over patient well-being. Prosecutors made clear that this was not a matter of negligence but an orchestrated campaign to exploit a vulnerable population. U.S. Attorney Paul Fishman stated, *"Par aggressively marketed a drug to elderly patients despite evidence of serious risks, and knowingly caused false claims to be submitted to Medicare and Medicaid."* The case underscored how Par's disregard for clinical boundaries and regulatory approvals translated into direct harm for patients and taxpayer-funded programs.

PRESS RELEASE

Par Pharmaceuticals Pleads Guilty and Agrees to Pay $45 Million to Resolve Civil and Criminal Allegations Related to Off-Label Marketing

Tuesday, March 5, 2013

For Immediate Release
Office of Public Affairs

New Jersey-based Par Pharmaceutical Companies Inc. pleaded guilty in federal court today and agreed to pay $45 million to resolve its criminal and civil liability in the company's promotion of its prescription drug Megace ES for uses not approved as safe and effective by the Food and Drug Administration (FDA) and not covered by federal health care programs, the Justice Department announced.

Chief Executive Officer Paul V. Campanelli pleaded guilty on behalf of Par before U.S. Magistrate Judge Madeline Cox Arleo earlier today in Newark, N.J., federal court. Judge Arleo fined Par $18 million and ordered $4.5 million in criminal forfeiture. Par also agreed to pay $22.5 million to resolve its civil liability.

Generic Drug Price-Fixing Conspiracy

Par Pharmaceutical was one of several companies named in a massive DOJ-led antitrust investigation that uncovered a sweeping conspiracy to inflate prices and allocate market share in the generic drug industry. The investigation, which began around 2016 and continues to yield charges and settlements, revealed that Par executives colluded with competitors like Teva,

Mylan, and Sandoz to fix prices on commonly used generics. Internal emails and phone records indicated that Par executives had coordinated with competitors to raise prices simultaneously, often after informal “market checks” or direct communication. These agreements covered critical drugs such as doxycycline and pravastatin, affecting millions of patients and inflating costs across Medicaid, Medicare, and commercial plans. DOJ officials described the network as a “textbook cartel” in which competitors became collaborators, agreeing not to undercut one another to maintain artificially high prices. Par’s role was not peripheral. In court filings and congressional reports, Par was consistently identified as a “core participant” in negotiations to divide markets and synchronize pricing. For example, in one instance, Par and its counterparts agreed to allocate customer accounts and set prices in advance to avoid competition — a blatant violation of the Sherman Antitrust Act. This type of behavior not only harmed consumers but undermined the foundational premise of the generic drug industry: to offer lower-cost alternatives to brand-name medications. By eliminating price competition, Par and others deprived public health systems of billions in potential savings. Lawsuits filed by state attorneys general and the federal government estimate that the price-fixing schemes may have inflated costs for certain generics by over 1,000%. While Par has not yet been criminally convicted in this case, it has reached civil settlements and remains under scrutiny. The weight of evidence — including coordinated price movements, documented collusion, and witness testimony — strongly supports the conclusion that Par engaged in intentional, calculated market manipulation.

PRESS RELEASE

Major Generic Drug Companies to Pay Over Quarter of a Billion Dollars to Resolve Price-Fixing Charges and Divest Key Drug at the Center of Their Conspiracy

Monday, August 21, 2023

For Immediate Release
Office of Public Affairs

DECISION AND ORDER
(PAR)

The Federal Trade Commission ("Commission") having initiated an investigation of certain acts and practices of Par Pharmaceutical, Inc. and Par Pharmaceutical Holdings, Inc., which are owned by TPG Partners VI, L.P. (collectively "Respondents") and Concordia Pharmaceuticals Inc. and its parent Concordia Healthcare Corp. (collectively "Concordia") and, Respondents having been furnished thereafter with a copy of a draft of Complaint that the Bureau of Competition proposed to present to the Commission for its consideration and which, if issued by the Commission, would charge Respondents with violation of Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45; and

Kickbacks and Misbranding in Long-Term Care Markets

Long before the Megace ES scandal, Par Pharmaceutical was already under fire for its aggressive and unethical promotional practices, particularly within the long-term care market. Whistleblower complaints filed under seal in the mid-2000s and later unsealed revealed that Par had for years provided unlawful incentives to nursing home operators, pharmacies, and healthcare professionals in exchange for preferential treatment. According to these complaints, Par used so-called "consulting agreements" to funnel kickbacks to key decision-makers. These contracts, often lacking clear deliverables, were structured to disguise payments as legitimate business expenses. In reality, they were used to induce facilities to stock and prescribe Par's

drugs over competing generics. Additional incentives included free starter packages, loyalty discounts, and payments for participation in “advisory boards” that functioned as promotional fronts. Federal investigators argued that these inducements violated the Anti-Kickback Statute and led to violations of the False Claims Act because they tainted the decision-making process for publicly reimbursed prescriptions. Moreover, Par’s tactics frequently blurred the line between branding and regulatory compliance. Sales teams often used unapproved promotional materials or claims that overstated efficacy, creating grounds for misbranding charges under the Food, Drug, and Cosmetic Act. In one deposition, a former Par executive admitted that the company’s long-term care division operated with “flexible ethics,” incentivized by internal performance metrics that rewarded sales over compliance. The result was a widespread culture in which regulatory boundaries were seen as obstacles rather than obligations. While some cases were settled quietly or dismissed on procedural grounds, the weight of the whistleblower allegations, combined with corroborating evidence from government investigations, paints a clear picture of a company that treated healthcare regulation as negotiable. These practices further confirm Par’s longstanding strategy of using fraud as a lever for commercial advantage.

RECENT MATTER

Santarus Secures $100M Settlement from Par Pharmaceuticals

09.2014

On September 22, 2014, Par Pharmaceuticals agreed to pay $100 million to Irell client Santarus Inc., now owned by Salix Pharmaceuticals, and the curators of the University of Missouri to settle the patent infringement dispute over Par's sales of a generic version of Zegerid. The case was scheduled for trial in the District of Delaware in November 2014. Par agreed to the settlement just three days before the pretrial conference. The Irell team included Morgan Chu and Amy Proctor.

Conclusion

Par Pharmaceutical's history of fraud reveals a consistent pattern of corporate misconduct driven by profit-maximizing incentives and a willingness to exploit systemic vulnerabilities. From the calculated endangerment of elderly patients through off-label promotion, to its central role in price-fixing conspiracies, to kickback-laden long-term care operations, the company has repeatedly engaged in deliberate, large-scale deception. What distinguishes Par's misconduct is not simply the volume of violations, but the systemic and intentional nature of each scheme.