Novo Nordisk

Modern medical fraud

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Executive Summary

Novo Nordisk A/S, the Danish pharmaceutical giant renowned for its diabetes and obesity treatments, has faced repeated legal challenges and investigations stemming from systemic fraudulent commercial practices that have compromised patient safety and driven up healthcare costs. The company has been accused of illegal marketing and kickbacks to pharmacy benefit managers (PBMs), pharmacies, and healthcare providers to secure preferred formulary placement and boost sales of its blockbuster drugs Victoza and Saxenda. In 2020, Novo Nordisk settled a major False Claims Act lawsuit by paying $45 million to resolve allegations that it offered undisclosed financial incentives disguised as rebates, speaker fees, and sham consulting agreements that induced overprescribing, circumventing federal anti-kickback laws designed to protect clinical integrity. Alongside these marketing abuses, Novo Nordisk is also at the center of controversy regarding the dramatic escalation of insulin prices in the United States. Investigative reports and lawsuits reveal that Novo Nordisk, alongside other insulin manufacturers, engaged in tacit coordination to raise list prices, using opaque rebate mechanisms to incentivize PBMs to favor higher-priced products. This rebate-driven pricing system has significantly increased out-of-pocket costs for many patients, especially those uninsured or underinsured, forcing some to ration or forego essential medications. The federal government, multiple states, and congressional committees have launched probes into Novo Nordisk's pricing and rebate practices, citing possible antitrust violations, false claims, and anti-kickback breaches. While Novo Nordisk has introduced patient assistance programs and minor pricing reforms, critics argue these efforts fall short of addressing the underlying systemic issues. The ongoing legal actions against Novo Nordisk exemplify the broader challenges of pharmaceutical pricing

transparency and ethical compliance in a complex healthcare marketplace, underscoring the urgent need for stronger oversight and reform.

Novo Nordisk

Founded in 1923, Novo Nordisk has evolved from a modest insulin manufacturer in Denmark to one of the leading global pharmaceutical companies specializing in diabetes care and obesity management. Its extensive product portfolio includes a range of insulin analogs—such as NovoLog, Levemir, and Tresiba—and GLP-1 receptor agonists like Victoza and Ozempic, which have revolutionized treatment for millions of patients worldwide. The company's revenues consistently exceed $25 billion annually, with a significant market share in the United States, Europe, and emerging markets. Novo Nordisk heavily invests in research and development, focusing on innovative biologics and next-generation therapies targeting chronic metabolic diseases. Despite its scientific contributions, Novo Nordisk's commercial practices have increasingly come under scrutiny. Over the past two decades, insulin prices in the U.S. have surged more than 200%, far outpacing inflation and wage growth, making diabetes management prohibitively expensive for many patients. While Novo Nordisk highlights its commitment to patient access through assistance programs and charitable initiatives, these efforts contrast sharply with aggressive marketing tactics and rebate strategies that critics argue prioritize profit over patient affordability. The company's expansive lobbying efforts and complex rebate negotiations with pharmacy benefit managers play a central role in shaping the drug pricing landscape. This duality of innovation and controversy has made Novo Nordisk a focal point in debates over pharmaceutical ethics, pricing transparency, and healthcare equity.

Illegal Marketing and Kickback Allegations

The 2020 settlement with the U.S. Department of Justice (DOJ) for $45 million marked a pivotal moment in exposing Novo Nordisk's extensive use of illegal kickbacks and deceptive marketing. The government alleged that Novo Nordisk deliberately structured financial incentives to PBMs, pharmacies, and healthcare providers to favor its diabetes and obesity drugs Victoza and Saxenda, often at the expense of safer or more cost-effective alternatives. These payments included undisclosed rebates, speaker fees for sham educational events, and consulting contracts lacking substantive services—all designed to reward high-volume prescribing and preferred formulary status. Internal documents revealed that sales representatives were coached to emphasize the benefits of these drugs aggressively, while minimizing discussion of potential adverse effects, including Victoza's known association with thyroid cancer in animal studies. The kickback schemes compromised physician independence, skewed clinical decisions, and inflated government healthcare spending via Medicare and Medicaid programs, which ultimately reimbursed these costly prescriptions. Furthermore, patient assistance programs touted by Novo Nordisk were allegedly used as tools within the kickback framework, funneling incentives indirectly to prescribers or PBMs rather than directly to patients in need. The DOJ characterized these practices as a direct violation of federal anti-kickback statutes and the False Claims Act, which prohibit inducements intended to influence federally funded healthcare decisions. Though Novo Nordisk denied wrongdoing and settled without admitting liability, the case underscored the company's willingness to engage in opaque financial dealings that undermine regulatory safeguards, raising concerns about broader industry practices where kickbacks distort market competition and jeopardize patient safety.

PRESS RELEASE

Novo Nordisk Agrees to Pay $58 Million for Failure to Comply with FDA-Mandated Risk Program

Tuesday, September 5, 2017

For Immediate Release
Office of Public Affairs

Payments Resolve Allegations Highlighted in DOJ Civil Complaint and Recently Unsealed Whistleblower Actions

Pharmaceutical Manufacturer Novo Nordisk Inc. will pay $58.65 million to resolve allegations that the company failed to comply with the FDA-mandated Risk Evaluation and Mitigation Strategy (REMS) for its Type II diabetes medication Victoza, the Justice Department announced today. The resolution includes disgorgement of $12.15 million for alleged violations of the Federal Food, Drug, and Cosmetic Act (FDCA) from 2010 to 2012 and a payment of $46.5 million for alleged violations of the False Claims Act (FCA) from 2010 to 2014. Novo Nordisk is a subsidiary of Novo Nordisk U.S. Holdings Inc., which is a subsidiary of Novo Nordisk A/S of Denmark. Novo Nordisk's U.S. headquarters is in Plainsboro, New Jersey.

PRESS RELEASE

Novo Nordisk Agrees to Pay $9 Million Fine in Connection with Payment of $1.4 Million in Kickbacks Through the United Nations Oil-for-food Program

Monday, May 11, 2009

For Immediate Release
Office of Public Affairs

Novo Nordisk A/S (Novo), a Danish corporation based in Bagsvaerd, Denmark, has agreed to pay a $9 million penalty for illegal kickbacks paid to the former Iraqi government. Novo agreed to pay the fine as part of a deferred prosecution agreement with the Department. The matter is part of the Justice Department's ongoing investigation into the U.N. Oil-for-Food program.

Coordinated Price Inflation and Rebate Manipulation

Novo Nordisk's contribution to the escalating insulin pricing crisis has drawn significant criticism and legal attention. Over the past two decades, insulin prices in the U.S. have tripled, making this essential medication unaffordable for many diabetic patients. Investigative reporting

and lawsuits have revealed that Novo Nordisk, alongside rivals Eli Lilly and Sanofi, engaged in tacit coordination to raise list prices in tandem, minimizing competition and maximizing profit margins. Unlike straightforward price hikes, Novo Nordisk implemented a sophisticated rebate system in which high list prices enabled it to offer substantial rebates to pharmacy benefit managers. These rebates created perverse incentives for PBMs to favor higher-priced insulins over lower-cost generics or biosimilars, as rebates often translated into higher profits for PBMs. This rebate-driven system effectively penalizes patients with high deductibles or those without insurance coverage, who face full list prices at the pharmacy counter, sometimes exceeding $500 per vial. Leaked internal communications revealed strategic planning to synchronize price increases with competitors, thereby maintaining market stability and minimizing the risk of losing formulary exclusivity. State and federal lawsuits argue this constitutes illegal price-fixing and anti-competitive conduct, as these actions distort market forces and artificially inflate healthcare costs. Congressional investigations have highlighted how Novo Nordisk's rebate practices undermine transparency and patient access, urging reforms that would decouple PBM profits from drug prices and increase pricing disclosures. While Novo Nordisk has introduced modest price caps and patient assistance initiatives, critics maintain that the fundamental rebate system remains unchanged, continuing to fuel high costs and barriers to care.

For Release

FTC Sues Prescription Drug Middlemen for Artificially Inflating Insulin Drug Prices

Caremark, Express Scripts, Optum, and their affiliates created a broken rebate system that inflated insulin drug prices, boosting PBM profits at the expense of vulnerable patients, the FTC alleges

September 20, 2024

Competition usually leads to lower prices as sellers try to win business. But in the upside-down insulin market, manufacturers—driven by the Big Three PBMs' hunger for rebates—increased list prices to provide the larger rebates and fees necessary to compete for formulary access, the FTC's complaint alleges. According to the complaint, one Novo Nordisk Vice President said that PBMs were "addicted to rebates." While PBMs' rebate pressures continued, insulin list prices soared. For example, the list price of Novolog U-100, an insulin medication manufactured by Novo Nordisk, more than doubled from $122.59 in 2012 to $289.36 in 2018.

Ongoing Legal and Regulatory Actions

Novo Nordisk remains subject to multiple active investigations and lawsuits at both federal and state levels. States including California, New York, and Illinois have initiated lawsuits alleging deceptive marketing practices and consumer fraud linked to inflated insulin prices and kickback schemes. Federal authorities, notably the Department of Justice and the Federal Trade Commission, continue probing whether Novo Nordisk's rebate and pricing strategies violate anti-kickback statutes, False Claims Act provisions, and antitrust laws. Congressional hearings have featured questioning of Novo Nordisk executives regarding their pricing policies, rebate structures, and the broader impact on patient affordability. The company's responses have

included promises of increased transparency and incremental price freezes, but these have been met with skepticism from policymakers and patient advocacy groups who argue that substantive change is necessary. Industry observers note that Novo Nordisk's case highlights systemic regulatory challenges in the pharmaceutical sector, where complex financial arrangements and market concentration allow companies to engage in potentially fraudulent conduct with limited immediate consequences. The outcomes of ongoing litigation and investigations may set important precedents for enforcement of anti-kickback and antitrust laws, influencing how pharmaceutical companies structure their pricing and marketing in the future.

Conclusion

Novo Nordisk's history of illegal marketing, kickbacks, coordinated price inflation, and rebate manipulation highlights significant ethical breaches and systemic issues within pharmaceutical industry practices. While the company has driven advances in diabetes treatment, its aggressive commercial tactics have contributed to unaffordable insulin prices and compromised the integrity of clinical decision-making. The ongoing legal and regulatory scrutiny underscores the urgent need for reform in drug pricing transparency, rebate oversight, and enforcement of anti-kickback statutes to protect patients and public health.