

Amgen Inc.

Modern medical fraud

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Executive Summary

Amgen Inc. (NASDAQ: AMGN), one of the largest biotechnology firms in the world, has long positioned itself as a pioneer in biologic therapeutics. However, beneath the surface of its innovation lies a disturbing record of regulatory violations, unethical sales practices, and criminal misconduct. A particularly damning episode in the company's history centers around a multi-year federal investigation that led to Amgen pleading guilty to illegally marketing its anemia drug Aranesp, resulting in a criminal conviction and fines exceeding \$762 million. The U.S. Department of Justice (DOJ) found that Amgen promoted off-label use of Aranesp, deliberately encouraging physicians to prescribe it at unsafe doses and for unapproved indications, despite clear FDA restrictions. Whistleblowers and internal documents revealed a systemic effort to game reimbursement systems and incentivize providers through illegal kickbacks. Beyond Aranesp, Amgen has also faced serious allegations tied to price inflation schemes, Medicaid fraud, and misrepresentations to investors. In 2023, the Federal Trade Commission (FTC) intervened to block Amgen's \$27.8 billion acquisition of Horizon Therapeutics, citing concerns that Amgen may use its dominant position to engage in exclusionary rebate practices to suppress competition. This legal scrutiny reaffirms concerns about Amgen's pattern of leveraging its market power in ways that undermine fair pricing and patient safety. The implications of Amgen's misconduct extend beyond shareholder value or isolated fines—they reveal how major biotech corporations may exploit the regulatory gray zones of the U.S. healthcare system for profit. The case also highlights the importance of sustained federal oversight and robust whistleblower protections. With continued legal probes, settlement payouts, and controversial acquisitions, Amgen's reputation is increasingly

overshadowed by its ethical failings, making it a compelling example of the intersection between pharmaceutical innovation and systemic fraud.

Company Background

Founded in 1980 and headquartered in Thousand Oaks, California, Amgen quickly rose to prominence as one of the original "biotech giants." Its mission statement emphasizes using science and innovation to improve lives, and its flagship drugs—including Epogen, Aranesp, Enbrel, Neulasta, and more recently, Repatha—have treated millions of patients worldwide. Amgen's commercial model blends advanced biologic drug development with aggressive patent protection, allowing it to maintain market dominance in several therapeutic areas, including oncology, nephrology, and rheumatology. Despite its reputation for scientific excellence, Amgen has long been scrutinized for its business tactics, including high drug pricing, controversial marketing strategies, and lobbying efforts. Over the years, it has amassed a powerful Washington presence, lobbying Congress on everything from patent law to Medicare reimbursement rules. Its financial success is staggering—reporting annual revenues upwards of \$26 billion as of 2023—but this profitability has often come at the cost of compliance with federal regulations. One of Amgen's most financially successful products, Aranesp (a long-acting erythropoiesis-stimulating agent), became a focal point of legal troubles in the 2000s. Allegations emerged that Amgen encouraged physicians to administer larger, more frequent doses of the drug to boost profits—even though higher doses were associated with severe side effects, including increased risks of stroke and death. These allegations not only led to significant legal consequences, but also tarnished the company's reputation in the medical community.

Off-Label Marketing and Aranesp Scandal

The most high-profile scandal in Amgen's history centers around the illegal promotion of Aranesp. Initially approved by the FDA in 2001 to treat anemia associated with chronic kidney disease and chemotherapy, Aranesp was a cornerstone of Amgen's product portfolio. However, the company soon began pushing the drug for off-label uses—particularly for cancer patients not undergoing chemotherapy—and at dosages not approved by the FDA. Amgen's sales representatives were reportedly instructed to promote these unapproved uses, despite explicit warnings from the FDA. Prosecutors later revealed that Amgen trained employees to dodge regulatory language during doctor meetings and to downplay the known risks of higher dosages. Furthermore, internal memos showed Amgen devised schemes to boost physician reimbursement, including bundling drugs together to maximize profits and offering volume-based discounts in exchange for increased Aranesp usage. These actions led to a major DOJ investigation, culminating in Amgen pleading guilty in 2012 to a misdemeanor criminal charge related to the misbranding of Aranesp. The company agreed to pay \$612 million in civil settlements and a \$136 million criminal fine—the largest-ever criminal settlement involving a biotechnology company at the time. Federal prosecutors stated that Amgen's conduct posed a serious threat to patient safety and demonstrated a pattern of prioritizing profit over compliance.

PRESS RELEASE

Amgen Inc. Pleads Guilty to Federal Charge in Brooklyn, NY.; Pays \$762 Million to Resolve Criminal Liability and False Claims Act Allegations

Wednesday, December 19, 2012

For Immediate Release
Office of Public Affairs

Biotech Giant Pleads Guilty to Illegally Introducing Drug into Market for Uses That the FDA Declined to Approve; Will Pay \$612 Million to Resolve False Claims Act Suits and \$150 Million in Criminal Penalties and Forfeiture

Kickback Schemes and Reimbursement Abuse

The DOJ case also unveiled widespread kickback schemes that Amgen used to drive Aranesp sales. These included offering cash incentives, speaker fees, and consulting agreements to doctors who prescribed the drug at high volumes. In some instances, the company covered travel and lodging costs for physicians attending promotional events disguised as educational seminars. Whistleblower lawsuits under the False Claims Act—many of which were later consolidated—documented how these incentives distorted medical judgment and led to unnecessary or unsafe prescriptions. Amgen also manipulated Medicare reimbursement systems by encouraging providers to bill for dosages that exceeded clinical necessity. This practice inflated Medicare and Medicaid costs, effectively defrauding taxpayers. Internal training materials even provided guidance on how to code these prescriptions to avoid detection by federal auditors. These activities not only led to civil liability but also prompted calls from members of Congress for stricter enforcement of anti-kickback statutes in the biotech sector.



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Amgen to pay \$25 million to settle kickback allegations

By Reuters

April 16, 2013 4:31 PM CDT · Updated April 16, 2013



(Reuters) - Amgen Inc has agreed to pay \$24.9 million to settle allegations that it provided kickbacks to long-term care pharmacy providers to entice them to use its Aranesp anemia drug instead of a rival medicine, the Department of Justice announced on Tuesday.

The DOJ charged that the world's largest biotechnology company violated the False Claims Act through kickbacks paid to Omnicare Inc, Kindred Healthcare Inc and PharMerica Corp in exchange for switching Medicare and Medicaid patients to Aranesp to treat their anemia.

FTC Antitrust Lawsuit Over Horizon Therapeutics Merger

In 2023, Amgen once again found itself in legal crosshairs—this time not over drug marketing but corporate consolidation. The Federal Trade Commission (FTC) filed a lawsuit to block Amgen's \$27.8 billion acquisition of Horizon Therapeutics. The FTC alleged that Amgen planned to use its existing rebate agreements with pharmacy benefit managers (PBMs) to stifle competition against Horizon's key products, Tepezza and Krystexxa. Though Amgen denied the allegations and characterized the suit as speculative, the FTC argued that Amgen had a "track record" of using bundling and rebates to block biosimilar competition. The case raised broader antitrust concerns over how large pharmaceutical companies use vertical integration and complex financial arrangements to maintain monopolies. Although a settlement was eventually reached in late 2023 allowing the merger to proceed under certain conditions, the episode underscored regulatory anxieties about Amgen's business practices.

Conclusion

Amgen's history offers a stark reminder that even companies built on scientific innovation are not immune to ethical and legal lapses. The Aranesp scandal exposed serious flaws in Amgen's corporate governance, from incentivizing risky off-label prescriptions to defrauding public insurance programs. The more recent FTC scrutiny over anticompetitive practices suggests that these issues are not relics of the past, but ongoing concerns in the company's strategic playbook.