ALM | LAW.COM

New York Law Journal

ANTITRUST TRADE AND PRACTICE

Upping the Dosage: Health Care and Pharma Antitrust Regulation in 2023

December 12, 2023

By **Karen Hoffman Lent**

And **Kenneth Schwartz**

Antitrust developments in the health care and pharmaceutical industries were exceptionally active in 2023. From the Federal Trade Commission's (FTC) challenge of a merger between Amgen Inc. (Amgen) and Horizon Therapeutics plc (Horizon), to joint agency withdrawal of well-established health care merger policy statements, to agency interest in pharmacy benefit managers (PBMs), we review some of the most notable antitrust activity in the health care and pharmaceutical industries over the past year.

Amgen/Horizon

Back in December 2022, Amgen, a California-based biotechnology company, announced its plans to acquire Horizon, an Irish biopharmaceutical company focused on medicines for rare and rheumatic diseases, for around $28 billion. In the announcement for the deal, Amgen noted that Horizon would add a complementary pipeline of medicines to the company's R&D portfolio, as in fact, none of Amgen's drugs compete with those of Horizon.

A lack of horizontal or vertical overlap did not deter Senator Elizabeth Warren from writing to the FTC to urge the agency to scrutinize the deal along with one other major pharmaceutical merger pending at the time. In her letter, Senator Warren expressed growing concern over the "rampant consolidation in the pharmaceutical industry and its impact on drug affordability and access in the United States."

Days after receiving the senator's letter, the FTC issued Amgen and Horizon a Second Request on Jan. 30, 2023.

After months of investigating and communicating with the companies, the FTC filed a complaint for a preliminary injunction in the U.S. District Court for the Northern District of Illinois on May 16, 2023, and lodged its administrative complaint on June 22. The agency was later joined by state attorneys general from six states: California, Illinois, Minnesota, New York, Washington and Wisconsin.

In its complaint, the FTC alleged that the acquisition would "enable Amgen to leverage its portfolio of blockbuster drugs to foreclose actual or potential rivals to

KAREN HOFFMAN LENT *and* KENNETH SCHWARTZ *are partners at Skadden, Arps, Slate, Meagher & Flom.*

Horizon's top-selling medications," giving it the ability and incentive to "entrench monopolies" over Horizon's drugs, Tepezza and Krystexxa, in PBM drug lists (also known as formularies). Complaint at 2, *F.T.C. v. Amgen and Horizon Therapeutics*, Case No. 1:23-cv-03053 (N.D. Ill. May 16, 2023). The FTC argued that the combined company could engage in potentially exclusionary rebating schemes and cross-product bundling in partnership with PBMs, which could agree to accept rebates in exchange for prioritizing Amgen's drugs and excluding those of its competitors.

In a press release statement in response to the FTC's complaint, Amgen revealed that it had been cooperating with the agency for months to address its questions and concerns. Amgen argued that it had demonstrated that the combination posed no legitimate competitive issues and even committed that it would not bundle the Horizon products that concern the FTC, which the agency alleged was its core issue with the transaction.

The Amgen/Horizon saga was remarkable for two reasons. First, the challenge was based on entrenchment and cross-bundling concerns. Second, it was the first challenge to a pharma merger in recent history.

Despite Amgen's efforts, the agency moved forward with its lawsuit. Then-director of the FTC Bureau of Competition, Holly Vedova, noted in announcing the lawsuit that the action was a "clear signal to the market: The FTC won't hesitate to challenge mergers that enable pharmaceutical conglomerates to entrench their monopolies at the expense of consumers and fair competition." *See* Press Release, Federal Trade Commission, "FTC Sues to Block Biopharmaceutical Giant Amgen from Acquisition That Would Entrench Monopoly Drugs Used to Treat Two Serious Illnesses" (May 16, 2023).

In August 2023, the FTC reached a proposed consent order with Amgen, prompting the six state attorneys general to dismiss their claims and allowing the transaction to close in September 2023. As part of the consent order, the combined company is prohibited from leveraging Amgen's drug portfolio to foreclose or disadvantage competitors to Tepezza or Krystexxa for 15 years, the very same remedy that the companies had proposed before the FTC's complaint was even filed.

The Amgen/Horizon saga was remarkable for two reasons. First, the challenge was based on entrenchment and cross-bundling concerns, a novel non-horizonal theory of harm for the agency. Second, it was the first challenge to a pharma merger in recent history, signaling to the industry that the agencies are likely to use forthcoming transactions as test cases to pursue novel theories of harm.

Scrutiny of Non-Reportable Transactions

We suspect that 2024 will bring continued scrutiny not only to transactions that meet the HSR threshold in the health care and pharmaceutical space, but to non-reportable deals as well.

In a speech at the Oliver Wyman Health Innovation Summit in Chicago in September, FTC Chair Lina Khan reported that FTC data show that "below the radar" deals (those under the HSR threshold) lead to market consolidation that escapes government review, as seen in the tech space. Chair Khan drew a cautionary parallel between a similar need to address any "blind spots" with respect to non-reportable deals in the health care and pharma space as the agency has done in the tech sectors.

This comment aligns with a June 2023 joint announcement by the FTC and the U.S. Department of Justice (DOJ) discussing proposed changes to the HSR Form that will require parties to provide details on previous acquisitions, including those under the HSR threshold, as a method to assess anticompetitive conduct.

This desire to evaluate past actions, including past acquisitions, seems to be a theme for the agencies going forward. As they look to broaden theories of harm and rationale for investigations and scrutiny, they are pushing for more comprehensive analyses by any means necessary.

Pharmacy Benefit Managers

Another continued area of focus for antitrust agencies this year was the role of PBMs in drug pricing and availability. PBMs are third-party companies that serve as intermediaries between insurance providers and pharmaceutical manufacturers—negotiating rebates, creating formularies or drug lists, processing claims and establishing drug networks, among other responsibilities.

Historically, the FTC found PBMs to substantially benefit consumers by keeping the costs of pharmaceuticals affordable. The FTC published nine letters between 2004 and 2014 that advocated against proposals to increase regulatory oversight and transparency of PBMs. However, in 2022, the FTC announced the issuance of compulsory orders to six of the largest PBMs to "scrutinize the impact of vertically integrated pharmacy benefit managers on the access and affordability of prescription drugs." *See* Press Release, Federal Trade Commission, "FTC Launches Inquiry Into Prescription Drug Middlemen Industry" (June 7, 2022).

This year, the FTC expanded its ongoing inquiry to include two group purchasing organizations (GPOs)—Zinc Health Services LLC and Ascent Health Services LLC. The companies join the investigation into CVS Caremark, Express Scripts Inc., Humana Pharmacy Solutions Inc., MedImpact Healthcare Systems Inc., OptumRx Inc. and Prime Therapeutics LLC.

In July, FTC Commissioners unanimously voted to issue a statement cautioning PBMs against reliance on the agency's prior advocacy statements related to their business that "no longer reflect current market realities." *See* Press Release, Fed. Trade Commission, "FTC Votes to Issue Statement Withdrawing Prior Pharmacy Benefit Manager Advocacy" (July 20, 2023).

Concerns about PBMs were integral to the FTC's challenge of the Amgen/Horizon merger. In the agency's Sept. 1 statement announcing the settlement in Amgen/Horizon, Chair Khan wrote that the "bundling and exclusionary rebating practices at issue in this matter" underscore the agency's deeper concerns about how pharmaceutical companies and PBMs may "work together to deprive Americans of access to affordable drugs." Statement of Chair Lina M. Khan, "In the Matter of Amgen, Inc. and Horizon Therapeutics plc" (Sept. 1, 2023).

Further, the DOJ is interested in exploring potential vertical concerns involving PBMs. In a speech on Oct. 26, 2023, Deputy Assistant Attorney General Andrew Forman stated that the Division has noticed the "trend toward a more concentrated market structure with a few massive health care companies with robust stacks of insurance companies, providers, PBMs, pharmacies and/or other services under the same roof." Andrew J. Forman, "Remarks at Health Care Competition Conference" (Oct. 26, 2023).

He explained that the impact of consolidation of PBMs is not yet easily ascertained, questioning if the consolidation has led to procompetitive effects or if it has or will cause anticompetitive consequences like increases in market share and prices or reductions in innovation. Changes in long-standing perspectives coupled with joint-agency interest in PBMs indicate that they may hold a more prominent place in the agencies' agenda in 2024.

Withdrawal of Health Care Policy Statements

In a February 2023 press release, the DOJ announced the withdrawal of "outdated" antitrust policy statements related to enforcement in health care markets, which included "Statements of Antitrust Enforcement Policy in Health Care" (1996)

and "Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations Participating in the Medicare Shared Savings Program" (2011). Five months later, on July 14, 2023, the FTC also announced the withdrawal of the 1996 and 2011 statements.

The policy statements—issued jointly by the FTC and the DOJ—had created certain antitrust safety zones to exempt certain health care mergers from agency scrutiny and not deter mergers, joint ventures, or other activities that could lead to lower health care costs. Their abrupt withdrawal ended 30 years of institutional guidelines on how to structure health care transactions.

In the DOJ's press release, Assistant Attorney General Jonathan Kanter stated that "[t]he health care industry has changed a lot since 1993, and the withdrawal of that era's out of date guidance is long overdue," and noted that the Division was set to "work to ensure that its enforcement efforts reflect modern market realities." Press Release, U.S. Department of Justice, Antitrust Division, "Justice Department Withdraws Outdated Enforcement Policy Statements" (Feb. 3, 2023).

Represented by over 30 pharmaceutical companies and state associations, PULSE's mission stresses how the FTC and DOJ's proposed changes to regulation for pharma mergers ultimately jeopardizes new treatments and cures for patients in need.

The FTC echoed those sentiments in its press release, adding that "the statements no longer serve their intended purpose of providing accurate guidance to market participants." *See* Press Release, Federal Trade Commission, "Federal Trade Commission Withdraws Health Care Enforcement Policy Statements" (July 14, 2023).

The move has not come without industry criticism, however. The American Hospital Association, for example, wrote that withdrawing all "guidance without consultation with the field is both unnecessary and reckless." Press Release, American Hospital Association, "FTC Withdraws Health Care Antitrust Enforcement Guidance" (July 17, 2023).

Partnership for the U.S. Life Science Ecosystem

With the increased antitrust attention on the life sciences sectors this year, industry leaders, particularly pharmaceutical companies, have responded to government activity by forming the Partnership for the U.S. Life Science Ecosystem (PULSE), a coalition dedicated to "raising awareness about the unique life sciences ecosystem and the importance of M&A in leveraging efficiency and experience across companies of all sizes." *See* About Us, PULSE for Innovation (last visited Dec. 3, 2023).

Represented by over 30 pharmaceutical companies and state associations, PULSE's mission stresses how the FTC and DOJ's proposed changes to regulation for pharma mergers ultimately jeopardizes new treatments and cures for patients in need.

Conclusion

The major antitrust developments in the health care and pharmaceutical space this year hint at the FTC and DOJ's agenda to explore novel merger review and aggressive enforcement in 2024. Given the recent statements by agency leaders, the subsequent effects of the long-awaited merger guidelines set to be decided in 2024, changes to the HSR Act Form and more, the FTC and DOJ will likely continue to up the dosage on antitrust activity in these industries next year.