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Pharma Cos. Should Prepare For New Drug-Rebate Scrutiny

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The pharmaceutical industry remains in the crosshairs of both government antitrust enforcers and private plaintiffs.

President Joe Biden's July 9 Executive Order on "Promoting Competition in the American Economy" directed the Federal Trade Commission to focus on "unfair anti-competitive conduct or agreements in the prescription drug industries."[1]

The FTC is now led by a group of aggressive enforcers of antitrust who have also made the pharmaceutical industry one of their top priorities. State attorneys general and private plaintiffs are similarly focused on the industry. In this context, one issue that has come under increased antitrust scrutiny is drug rebating practices.

Last year, Congress directed the FTC to prepare a report on what it called "an increasingly common anti-competitive behavior potentially distorting the U.S. biopharmaceutical market known as rebate walls."[2] In May 2021, the FTC voted 4-0 to release its report, which concluded that certain drug rebate practices can have anti-competitive effects.[3]

The U.S. Food and Drug Administration has also recently made comments expressing concern about the potential for drug rebating practices to harm competition.[4] Drug rebating practices have also been the subject of significant private litigation between rival drug manufacturers.

This article describes some of the key antitrust issues relating to drug rebates that have recently arisen, including the concerns that the FTC and other government bodies have expressed about rebating practices, and how civil litigation over rebating practices has played out.[5]

The article also explains some of the legitimate and procompetitive reasons why pharmaceutical companies provide rebates for prescription drugs, which typically involve providing customers with lower prices and, as such, may reflect strong competition, rather than impede it.

Given the intense scrutiny on drug pricing and rebating practices, pharmaceutical companies need to be prepared to address and defend pricing strategies if challenged by a government enforcer or private plaintiff.

Background on Drug Pricing and Rebates

Multiple industry participants have a role in affecting the prices that customers pay for prescription drugs. Drug manufacturers develop branded drugs and set list prices for those drugs.[6] Wholesalers purchase large quantities of brand drugs directly from the manufacturers, and resell those drugs to pharmacies and other drug retailers.

Drug consumers — i.e., patients — acquire drugs from pharmacies, and usually pay for them with assistance from a health plan.

Health plans, in turn, typically contract with pharmacy benefit managers for the management of their prescription drug benefits. A health plan's PBM will typically negotiate with the drug manufacturer for a rebate. Rebates on prescription drugs are frequently paid directly from manufacturer to the PBM, and then passed on in some form to the health plan.

PBMs will typically offer a drug manufacturer a more favorable position on the PBM's formulary as a means to encourage the branded manufacturer to grant a higher level rebate. Rebates are frequently calculated as a percentage of a drug's list price.

Antitrust Scrutiny of Drug Rebates

In July 2020, Congress directed the FTC to study the competitive effects of so-called rebate walls, which a House of Representatives report stated occurred "when a pharmaceutical manufacturer couples volume-based discounts with retaliatory measures such as the clawback of rebates when a competitor product is granted formulary access."[7]

In May 2021, the FTC's staff report to Congress emphasized that the FTC was closely scrutinizing pharmaceutical companies' rebating practices.[8] The report expressed concern about a situation where "a dominant pharmaceutical manufacturer uses rebate strategies in its contracts with third party payers to maintain market power, by giving its products preferred status in drug formularies, and to prevent sales of competing products."[9]

The report expressed the view that when a manufacturer conditions rebates on preferential formulary access, or "market share" requirements, then that could provide the PBM and health plan with the financial incentive to exclude lower-cost, equally effective drugs from their formularies, which could have the effect of increasing overall drug prices borne by the market. The FTC report noted that "[t]he cost implications are particularly significant for biologics, given their generally higher costs relative to small molecule drugs."[10]

The FTC report expressed concern that such rebating practices could "give payers strong incentive to block patient access to lower-priced medicines," "increase overall drug spending," and "reduce incentives for biotechnology companies to develop new medicines."[11]

Additionally, the report noted that a group within the FTC has been formed to "consider rulemaking, including competition rules with respect to pharmaceutical industry practices."[12] The report

reiterated that the FTC "will continue to use its panoply of powers to promote competition in pharmaceutical markets.

It will investigate and, where the facts warrant, challenge exclusionary conduct by pharmaceutical firms and third-parties that threatens to delay new entry, keep prices artificially high or deter innovation, and deny patients access to competing treatments."[13]

The FTC report did not appear to address the fact that drug rebates generally result in lower prices. In fact, rebates are often granted by a drug manufacturer as a result of a highly competitive process — managed by the PBM — as a means to reduce the overall drug costs faced by health plans. Essentially, PBMs demand better prices in return for better formulary treatment.

In fact, research by the U.S. Department of Health and Human Services Office of Inspector General showed that rebates can lead to lower prescription drug costs in Medicare Part D.[14] The FTC report did, however, acknowledge that the analysis of rebating practices is highly fact-specific, noting that, to demonstrate a violation of the antitrust laws, a plaintiff may need to establish facts regarding "market definition and relative market power, the extent of market foreclosure, contract duration, anti-competitive effects and lack of potential countervailing procompetitive justifications, and a customer's practical ability to terminate agreements."[15]

Beyond this congressionally mandated report, the FTC has also investigated rebating practices in certain individual cases. For example, in June 2019, Johnson & Johnson disclosed that the FTC issued it a civil subpoena as part of an antitrust investigation into its contracts surrounding Remicade.[16]

Civil Antitrust Litigation Concerning Pharmaceutical Rebates

Private antitrust challenges to rebating practices by brand manufacturers have met with decidedly mixed results. For example, in Shire U.S. Inc. v. Allergan Inc.,[17] Shire accused rival dry-eye medication manufacturer Allergan of violating the antitrust laws by allegedly offering bundled rebates or rebates conditioned on formulary exclusivity to major Medicare Part D plans for Allergan's drug Restasis.[18]

Shire asserted that Allergan's efforts resulted in a "stranglehold on about 90 percent of the Part D market" for dry-eye drugs.[19] The U.S. District Court for the District of New Jersey in 2019 dismissed the complaint for failure to plausibly define the relevant market and because the requisite anti-competitive conduct had not been pleaded, noting that "neither bundled rebates nor exclusive dealing contracts are inherently anti-competitive. In fact, both can be procompetitive and potential anti-competitive effects are subject to a fact-sensitive analysis."[20]

In In re: Direct Purchaser Insulin Pricing Litigation, a putative class of wholesalers alleged that certain insulin drug manufacturers and PBMs engaged in a "commercial bribery" scheme, conspiring to raise the prices of insulin drugs in order to increase the fees manufacturers paid to PBMs, and that some PBMs did not pass on to their plan sponsors all rebates received for insulin drugs.[21]

In July, the District of New Jersey dismissed the antitrust claims on the grounds that the named plaintiffs lacked antitrust standing and failed to allege plausibly parallel conduct suggestive of an antitrust conspiracy.[22] However, the court allowed the plaintiffs' parallel Racketeer Influenced and Corrupt Organizations Act claims to proceed,[23] and the plaintiffs have sought to appeal the dismissal of their antitrust claims.[24]

In Pfizer Inc. v. Johnson & Johnson, Pfizer claimed that J&J's rebates for its infliximab medication, Remicade, were anticompetitive and "led to the near-total foreclosure of Inflectra," Pfizer's competing infliximab medication.[25] In 2018, the U.S. District Court for the Eastern District of Pennsylvania denied J&J's motion to dismiss, finding that, "Pfizer's Complaint sufficiently alleges that it has suffered an antitrust injury as the result of J&J's anticompetitive conduct.

J&J's efforts to foreclose Pfizer from the market, as Pfizer has alleged, have led to increased prices for consumers and limited competitive options for end payors, providers, and patients."[26] J&J also faced similar class action claims from pharmacies and wholesalers.[27]

Similarly, in In re: EpiPen — Epinephrine Injection, USP — Marketing, Sales Practices and Antitrust Litigation, Sanofi's antitrust claims alleging that Mylan's rebates for EpiPens excluded Sanofi from the relevant market initially survived a motion to dismiss.[28] But in December 2020, after extensive discovery, the U.S. District Court for the District of Kansas granted Mylan's motion for summary judgment, finding that Sanofi failed to prove that Mylan's rebate contracts substantially foreclosed competition, or that PBMs were coerced into accepting Mylan's rebates. Sanofi has appealed.[29]

Looking Forward

In light of the Democratic majority on the FTC, it appears likely that there will be increased FTC scrutiny of rebating practices in the near future. Commissioner Rohit Chopra criticized rebate walls, calling them "secretive kickback practices" that are "worrisome" and "warrant more serious attention."[30] Commissioner Rebecca Kelly Slaughter called rebates "secretive," asserting that they "favor larger competitors who can offer or demand bigger rebates" and calling for careful scrutiny of such practices.[31]

By contrast, Commissioners Christine Wilson and Noah Joshua Phillips called for their colleagues to avoid "sweeping rhetorical condemnations of industry practices," pointing out that "not every rebate is anti-competitive, not every reason for high drug prices is a violation of the antitrust laws."[32] Wilson and Phillips noted that "regulatory regimes prescribed by law create barriers to entry" and under similar legal regimes, such as intellectual property, "protections encourage innovation by permitting innovators to exclude competition for a set amount of time."[33]

Several current commissioners have expressed the opinion that the FTC's enforcement authority under Section 5 may allow the commission to challenge business practices that may be more difficult to challenge under a more traditional antitrust analysis.[34]

Pharmaceutical companies and other industry stakeholders should carefully consider their rebating strategies and positions in light of the current enforcement environment.

Correction: A previous version of this article incorrectly stated the date of the summary judgment decision in Sanofi. The error has been corrected.

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Disclosure: Stock and Parrott represented Allergan in Shire v. Allergan.

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[1] Executive Order on Promoting Competition in the American Economy (July 9, 2021), available at https://www.whitehouse.gov/briefing-room/presidential-actions/2021/07/09/executive-order-on-promoting-competition-in-the-american-economy/ ("Americans are paying too much for prescription drugs and healthcare services . . . .").

[2] House Report 116-456 published in the Congressional Record (Dec. 27, 2020), available at https://www.congress.gov/116/crpt/hrpt456/CRPT-116hrpt456.pdf) that accompanied H.R. 7668, Financial Services and General Government Appropriations Bill, 2021.

[3] Federal Trade Commission Report on Rebate Walls (May 28, 2021), available at https://www.ftc.gov/system/files/documents/reports/federal-trade-commission-report-rebate-walls/federal_trade_commission_report_on_rebate_walls_.pdf.

[4] Remarks from FDA Commissioner Scott Gottlieb, M.D., as prepared for delivery at the Brookings Institution on the release of the FDA's Biosimilars Action Plan (July 18, 2018), available at https://www.fda.gov/news-events/press-announcements/remarks-fda-commissioner-scott-gottlieb-md-prepared-delivery-brookings-institution-release-fdas.

[5] Unless otherwise mentioned, Congressional proposals to modify federal laws concerning rebating practices, state laws, anti-kickback statutes, RICO statutes, and other non-antitrust laws are beyond the scope of this article.

[6] The pricing and distribution process of generic drugs differ from those of brand drugs. The focus of this article is primarily on branded drug pricing.

[7] House Report 116-456 published in the Congressional Record (Dec. 27, 2020), available at https://www.congress.gov/116/crpt/hrpt456/CRPT-116hrpt456.pdf) that accompanied H.R. 7668, Financial Services and General Government Appropriations Bill, 2021.

[8] Federal Trade Commission Report on Rebate Walls (May 28, 2021), available at https://www.ftc.gov/system/files/documents/reports/federal-trade-commission-report-rebate-walls/federal_trade_commission_report_on_rebate_walls_.pdf.

[9] Id.

[10] Id.

[11] Id.

[12] Id.

[13] Id.

[14] U.S. Dep't of Health & Human Serv's, OEI-03-19-00010, Rebates for Brand-Name Drugs in Part D Substantially Reduced the Growth in Spending from 2011 to 2015 (2019).

[15] 15 Federal Trade Commission Report on Rebate Walls (May 28, 2021), available at https://www.ftc.gov/system/files/documents/reports/federal-trade-commission-report-rebate walls/federal_trade_commission_report_on_rebate_walls.pdf.

[16] Johnson & Johnson, Quarterly Report (Form 10-Q) 50 (June 30, 2019).

[17] Shire U.S. Inc v. Allergan Inc., 375 F. Supp. 3d 538 (D.N.J. 2019). Stock and Parrott represented Allergan in this matter.

[18] Shire US Inc. v. Allergan, Inc., 375 F. Supp. 3d 538, 540 (D.N.J. 2019).

[19] Mem. in Supp. of Shire's Opp'n to Defs' Mot. to Dismiss at 8, Shire US Inc. v. Allergan, Inc., 375 F. Supp. 3d 538 (D.N.J. 2019) (No. 17-7716).

[20] Shire US Inc. v. Allergan, Inc., 375 F. Supp. 3d 538, 557 (D.N.J. 2019).

[21] In re Direct Purchaser Insulin Pricing Litig., No. 320-cv-3426, 2021 WL 2886216, at *3 (D.N.J. July 9, 2021).

[22] Id. at *7-10.

[23] Id. at *11-20.

[24] Motion for Entry of Judgment, Dkt. No. 163, In re Direct Purchaser Insulin Pricing Litig., No. 320-cv-3426 (D.N.J. Aug. 5, 2021).

[25] Complaint at 43, Pfizer Inc. v. Johnson & Johnson, No. 17-cv-04180-JCJ (E.D. Pa. Sept. 20, 2017).

[26] Pfizer Inc. v. Johnson & Johnson, 333 F. Supp. 3d 494, 502 (E.D. Pa. 2018).

[27] Walgreen Co. v. Johnson & Johnson, 950 F.3d 195, 197 (3d Cir. 2020) (holding that Walgreen's lawsuit was not prohibited by an anti-assignment provision).

[28] In re EpiPen (Epinephrine Injection, USP) Mktg., Sales Pracs. & Antitrust Litig., No. 17-MD-2785-DDC-TJJ, 2017 WL 6524839, at *5-19 (D. Kan. Dec. 21, 2017).

[29] In re EpiPen (Epinephrine Injection, USP) Mktg., Sales Pracs. & Antitrust Litig., 507 F. Supp. 3d 1289, 1343, 1355 (D. Kan. 2020).

[30] U.S. Fed. Trade Comm'n, Statement of Commissioner Rohit Chopra Regarding the Commission's Report of Pharmacy Benefit Manager Rebate Walls (2021).

[31] U.S. Fed. Trade Comm'n, Statement of Commissioner Rebecca Kelly Slaughter Regarding the Commission's Report to Congress on Rebate Walls (2021).

[32] U.S. Fed. Trade Comm'n, Statement of Commissioners Christine S. Wilson and Noah Joshua Phillips Regarding the Commission's Report to Congress on Rebate Walls (2021).

[33] Id.

[34] Statement of Chair Lina M. Khan Joined by Commissioner Rohit Chopra and Commissioner Rebecca Kelly Slaughter on the Withdrawal of the Statement of Enforcement Principles Regarding "Unfair Methods of Competition" Under Section 5 of the FTC Act (July 1, 2021), available at https://www.ftc.gov/system/files/documents/public_statements/1591498/final_statement_of_chair_khan_joined_by_rc_and_rks_on_section_5_0.pdf.