

FTC Must Tackle Anti-Competitive Drug Rebate Practices

By **David Balto** (3:22 PM EDT) **May 17th, 2019 in Law 360**

Pharmaceutical manufacturers have implemented a strategy to block and delay entry of new innovative drugs from the market through a contracting practice that creates what is known as a “rebate wall” or “rebate trap”.[1] While rebates can be procompetitive if they lead to lower prices for consumers, some drug manufacturers are structuring rebates to limit competition from rivals in an effort to protect their monopolies.



David Balto

This article sets forth how the Federal Trade Commission can examine and challenge rebate walls. First, this article provides a detailed explanation of rebate walls. Second, it outlines how they harm consumers. Third, it provides a summary of how rebate walls are currently being challenged by pharmaceutical manufacturers in the courts. Fourth, this article explains how current bundling discount law should be applied. And finally, it concludes that the FTC is well-equipped to tear down these anti-competitive rebate walls.

Pharmaceutical manufacturers construct rebate walls when they use their dominant market position to secure preferred formulary access for their products by offering lucrative incentives to payors, including pharmacy benefit managers and health insurers, in the form of volume-based rebates.

These rebates are often offered across multiple products, indications and therapeutic specialties, which cannot be matched by new and innovative therapies. When a rebate wall is successfully erected by a market-dominant manufacturer, a payor faces strong financial disincentive to grant access to new and innovative therapies, because doing so would result in punitive action by the market-dominant firm that would result in the loss of hundreds of millions in guaranteed rebate dollars for the payor.

This condition creates a “trap” for payors who would otherwise be inclined to grant formulary access to therapies that are newer and more innovative, yet lack established volume and subsequent potential for rebate revenue. In many cases, these actions prevent patients and physicians from seriously considering new more efficacious medications at competitive prices.[2]

Increasingly, rebate walls and the competitive risks they pose are being scrutinized. For example, in response to President Donald Trump’s blueprint to lower drug prices, a number of drug manufacturers described how the rebate wall leads to higher prices.[3] In January 2019, the U.S. Department of Health and Human Services proposed a rule that would fundamentally change the way rebates are structured in the Medicare Part D program, in part to address the impact bundled rebates have on patient choice and innovation.[4]

In response to the HHS proposed rule, some drug manufacturers again described how rebates harm competition.[5] Major pharmaceutical firms such as Pfizer and Shire PLC have filed antitrust suits in blockbuster drug markets challenging rebate walls as antitrust violations.[6] And, Novartis’ CEO called for action stating “we need to tear down the rebate wall and create better contracting models that help patients” obtain access to cost-saving treatments.[7]

Meanwhile, HHS Secretary Alex Azar called on Congress to immediately pass a law to end all rebates that drug manufacturers pay to PBMs and payors.[8]

Rebate Walls Explained

Take a hypothetical market that includes Product A, which is approved by the U.S. Food and Drug Administration to treat rheumatoid arthritis and five other conditions. Assume that the price for an annual supply of Product A is \$50,000, but a rebate reduces the cost to the payor to \$25,000.[9] Now assume that an innovative branded drug or biosimilar Product B enters the market at an annual price of \$10,000, but only has FDA approval for rheumatoid arthritis. One would think that shifting new rheumatoid arthritis patients to Product B would save the payor substantial money (\$10,000 vs. \$25,000), but due to the rebate wall, that is not the case.

By switching rheumatoid arthritis patients to the less expensive Product B, the payor would lose its rebate from the manufacturer of Product A across all of its volume of Product A, which includes rheumatoid arthritis and five other autoimmune conditions. In other words, while the payor would save money for its rheumatoid arthritis patients, it would now need to pay full-price of \$50,000 annually (vs. \$25,000) for Product A for patients with the other five conditions. Thus, the payor would have to spend twice as much on the nonrheumatoid arthritis patients because of the loss of the rebate and would actually pay more in total if it provided a rheumatoid arthritis patient with access to Product B.[10]

The list price serves as a penalty price if the payor tries to shift to a competing drug. An entrant would have to immediately seize nearly all the patients in the market for the payor to save money.[11] This is nearly impossible in the drug industry because some patients will not switch regardless of price if the incumbent drug is working for them.

Rebate walls are effective at barring new entry because the rebates are typically based on volume and structured in such a way as to make it economically prohibitive for a payor to replace the incumbent drug with a competing drug.[12]

Bundling of Indications

An incumbent branded drug manufacturer with a blockbuster drug that treats multiple indications may make its rebates contingent on preferred or exclusive formulary position across all its indications.[13] This can prevent entry of a newly approved product with superior efficacy in only one indication, even if the new entrant offers a greater rebate. Because the new product has few prescriptions, if any, even a larger rebate will not overcome the potential loss of the rebate dollars from the market-leading product. This can be a complete bar to entry on to a payor's drug formulary when the entrant lacks the established volume or multiple indications.

Bundling a Portfolio of Drugs

An incumbent branded-drug manufacturer that offers a number of drugs may condition its rebates to payors who buy all or most of their prescription drugs through the branded manufacturer. If the payor falls below a certain amount of purchases, then it loses this rebate on all of its purchases. This rebate wall creates a strong disincentive for payors to put a new entrant's unique competing drug on their formularies, even if it provides a more effective treatment for the patient. Thus, an incumbent can prevent an entrant that does not have a portfolio of drugs and/or lacks the established volume from obtaining access to a payor's formulary altogether.

Rebate Walls Harm Consumers

Rebate walls harm patients in a number of ways. First, rebates paid by the drug manufacturers do not flow down to patients.[14] Second, rebates actually increase patients' out-of-pocket expenses and cause them to pay higher co-insurance payments[15] because they are based on a drug's list price not the net price paid by the payor.[16] Third, rebate walls distort the integrity of drug formularies and step therapies, to the detriment of patients.

PBMs and insurers design drug formularies and step therapies, and they generally provide preferred access to the drug manufacturers that pay the highest rebates, as opposed to the efficacy and safety of the drugs in question. Under step therapies, also known as fail first policies, patients are forced to try a drug preferred by the payor before being approved to use a drug originally prescribed by their doctors.[17]

As a result, patients miss out on obtaining more effective treatments sooner. This raises the costs for patients because they need to try a drug preferred by the payor and possibly a second preferred drug before gaining access to more effective treatment.

By locking new entrants out of formulary access and raising their costs to bringing their products to market, rebate walls make it more likely that such entrants will be discouraged from making the sizable investment in research and development in certain drugs and/or indications. Decisions to abandon R&D efforts decrease innovation and unquestionably harm competition and patients.

In fact, according to Pfizer CEO Ian C. Read during a Q2 2018 earnings call, "removal of the rebates ... will be very beneficial to patients and our industry, especially ... those companies who are launching new products over the next 5 years or so would remove ... rebate trap, whereby access is denied to innovative products because of a strong position of another product with its rebates."[18]

And former FDA Commissioner Scott Gottlieb fears that drug manufacturers are hamstringing competition through rebates.[19] His concern is that these contracting practices create disincentives for drug manufacturers to invest in the development of new innovative drugs, which harms consumers.[20]

Rebate Walls in the Courts

The rebate wall has significant impact on patient welfare and has recently been the center of some high-stakes litigation.

Pfizer v. Johnson & Johnson

In 2017, Pfizer brought an antitrust suit against Johnson & Johnson alleging that J&J used a variety of contractual practices to stifle Pfizer's entry into the \$4.8 billion infusion administered therapies market.[21] In November 2016, Pfizer entered the market with its biosimilar Inflectra to compete against J&J's Remicade.

Within weeks of the Inflectra launch, J&J began to deploy its "Biosimilar Readiness Plan," which allegedly involved a multipronged anti-competitive scheme designed to block insurers from reimbursing, and providers from purchasing, Inflectra, or other biosimilars.[22] The scheme included exclusive contracts for Remicade, rebates based on the bundling of

existing (incontestable) and new (contestable) infliximab patients, and multiproduct (bundled several drugs and medical devices for providers) bundling.[23]

Pfizer alleged that the contracts resulted in Inflectra not appearing on the insurance company's medical policy or, in the alternative, being designated as a "fail first" product meaning that it would only be reimbursed if Remicade was first tried, but failed to help the patient.[24] Pfizer alleged that these tactics created a "rebate trap" that prevented Pfizer and other competitors from competing with Remicade.[25] Because of these exclusionary practices, roughly 90% of all providers have decided not to purchase Inflectra at all, despite its lower cost.[26]

Last year, Pfizer's claims survived a motion to dismiss.[27] Following United States Court of Appeals for the Third Circuit case law, the district court held that bundled rebates can be anti-competitive when they foreclose competition in a competitive market by linking it to a noncompetitive market.[28] Specifically, the district court found that bundling Remicade's incontestable (legacy patients) demand could foreclose competition for new infliximab patients and deprive new infliximab patients (and their insurers) of the ability to make a meaningful choice between Remicade and Inflectra.[29]

Shire v. Allergan

Shire sued Allergan in 2017 alleging a similar pattern of anti-competitive conduct in the \$1.5 billion market for drugs for dry eye disease used in the Medicare Part D plan.[30] Shire alleged that it could not successfully enter the Medicare Part D market with a superior drug, Xiidra, which had similar pricing as the incumbent Allergan drug, Restasis, because of Allergan's exclusionary arrangements and bundled rebates with Medicare Part D plans.[31]

Shire alleged that Xiidra is approved to treat more signs and symptoms of dry eye disease than Allergan's Restasis and also does not need to be used in conjunction with a topical steroid, which Allergan's Restasis often does.[32] Shire also alleged that many patients using Restasis had adverse reactions or did not improve.[33] Despite the advantages of Xiidra, payors did not have the economic incentive to switch to the new drug because they would lose rebates not just on Restasis, but on the rest of Allergan's bundled drug portfolio.

As one plan told Shire, "You could give [Xiidra] to us for free, and the numbers still wouldn't work." [34] This tactic has allowed Allergan's Restasis to maintain a roughly 90% market share despite the entry of a new and improved drug.

On March 22, 2019, the district court granted Allergan's motion to dismiss the complaint for two reasons.[35] First, the district court held that Shire failed to plead a proper relevant market because the Medicare Part D dry eye disease market is "unduly narrow because it excludes others, notably commercial payers, to whom Plaintiff can sell Xiidra".[36] Second, Shire failed to allege the requisite anti-competitive conduct. Shire failed to allege that Allergan has "monopoly power over the" drugs it allegedly bundled with Restasis or that Shire "did not have other available products that it could offer ... as part of a bundled rebate" to Medicare Part D plans.[37]

The district court also questioned whether the conduct was sufficiently exclusionary because the contracts at issue were short in duration (i.e., one-year contract).[38]

The Proper Law to Be Applied to Rebate Walls

Three Third Circuit decisions demonstrate that exclusionary bundled discounts can be anti-

competitive under the antitrust laws. These decisions depart from the U.S. Supreme Court's decision in *Brooke Group*, which applied a tough standard to predatory pricing cases.[39] If a case only relates to discount pricing, a court will likely apply the *Brooke Group* price test, which finds such pricing illegal where it is below cost and the defendant can recoup its losses from below cost pricing.

The key to bringing a case based on rebate walls is to focus on whether the bundled discounts penalize PBMs and payors for selecting a competing drug on their formularies such that the bundled discounts are designed to exclude rivals from a properly defined market.

In *LePage's v. 3M*, the Third Circuit held that such discounts by a monopolist may be condemned as exclusionary under the rule of reason when single-product rivals cannot match the multiproduct discount.[40] The Third Circuit recognized that exclusionary conduct via bundling was a distinct cause of action separate and apart from predatory pricing. *LePage's* was competitively disadvantaged because it did not have a similar breadth of office supply products, and the Third Circuit concluded that there was no legitimate business justification for 3M's bundled discount that was really designed to exclude *LePage's* from the market.

In 2012, the Third Circuit condemned a loyalty discount program in *ZF Meritor LLC v. Eaton Transmission Corporation*. [41] Eaton, the leading maker of heavy-duty truck transmissions with 80% market share, offered loyalty discounts to all the consumers in the market. The Third Circuit held that a monopolist offering above-cost discounts conditioned upon the acceptance of additional nonprice restrictions violates the antitrust laws if the restraints constitute "de facto partial exclusive dealing." [42] The Third Circuit made clear that the Supreme Court's defendant-friendly price cost test of *Brooke Group* is appropriate when the conduct only relates to pricing. [43]

In 2016, the Third Circuit revisited this exclusionary conduct theory in a pharmaceutical case, *Eisai v. Sanofi-Aventis*, involving contracts for the anti-coagulant drug *Lovenox*. [44] There the Third Circuit reaffirmed its holding in *LePage's*, but declined to extend the reasoning to this case because it did not involve conditioning discounts on purchases across various product lines.

Instead, the case involved different types of demand for the same product (new contestable and existing incontestable patients). *Eisai* lost on the facts, as the Third Circuit held that it did not present sufficient support for its theory of harm. *Eisai's* allegation that Sanofi's loyalty discounts were an anti-competitive de facto exclusive dealing arrangement was rejected because there was no evidence of foreclosure. Nonetheless, the Third Circuit's decision is noteworthy because it also rejected Sanofi's argument that the *Brooke Group* price-cost test should have been applied.

In addition to the Third Circuit case law, professor Steve Salop's recent article "The Raising Rivals' Cost Foreclosure Paradigm, Conditional Pricing Practices, and the Flawed Incremental Price-Cost Test," helps explain why conditional pricing practice allegations should be examined under the raising rivals cost foreclosure paradigm and not the predatory pricing paradigm. [45] Salop explains how these conditional pricing practices are not really about prices, but about structuring markets to restrict access to competitors. [46]

Conditional pricing practices aim to raise rivals' cost to enter markets, and in the case of drug markets these additional costs can be insurmountable. For a new entrant to compete against an incumbent that has entered into contracts with payors that provide the payors

with conditional discounts based on the percentage of purchases or multiproduct bundled discounts, the new entrant must be able to offer a replacement bundle of prescription drugs for the payors to even consider switching.

According to Salop, the Third Circuit's approach is sound legal and economic policy. While the Brooke Group's price-cost test should be used when the discount relates only to pricing, Salop makes a good case that the law is better off using the foreclosure paradigm for conditional pricing practices.[47]

The Rebate Wall is Ripe for an FTC Solution

Over the past two decades, antitrust enforcement has played a crucial role in efforts to prevent anti-competitive conduct and keep pharmaceutical markets competitive. The FTC has successfully brought cases against dominant pharmaceutical manufacturers that have used a wide variety of anti-competitive strategies designed to prevent rivals from competing. Some of these strategies include entering into patent settlement agreements with cash payoffs that keep generics off the market and gaming the regulatory system to prevent and delay generic drug competition by refusing to supply generic firms with samples needed to manufacture more affordable generic alternatives.

The FTC has correctly recognized that some pharmaceutical manufacturers will engage in conduct that does not benefit consumers but serves simply to extend their monopolies. In those situations, the FTC has appropriately taken action.

Moreover, the FTC has an important role as a steward of antitrust policy to examine problems in antitrust jurisprudence and to advocate for the best result. The agency has always been committed to ensuring that its enforcement and policy efforts keep pace with changes in the marketplace so it can promote competition and innovation, protect consumers and shape the law.

To that end, in June of 2014, the FTC and the U.S. Department of Justice held a joint workshop where they invited legal and economic antitrust experts to discuss the topic of loyalty, bundled and conditional pricing practices.[48] The FTC heard presentations that explained how discounts could be used as a price penalty that could eliminate any real competition; how a monopolist could enter into exclusive arrangements with customers before the entrant arrives to provide a counterbid; and how a monopolist could offer bundled product discounts taking advantage of a nonlevel playing field. Accordingly, the FTC, which already has a wealth of experience in the pharmaceutical industry, is well equipped to use its expertise on conditional pricing to examine these practices.

The timing is right for developing meaningful and fact-based policy that can address anti-competitive rebate wall schemes. The FTC is currently holding a series of hearings on a wide range of topics, including issues that impact drug prices. These hearings aim to inform the FTC in crafting its policy and enforcement goals as it faces new challenges in a number of industries. As part of these hearings, the agency has already heard drug price concerns from consumer advocates and other interested parties on their panels and in submitted comments.

While this preliminary work to lower drug prices is a good start, it is time for the FTC to make some concrete decisions regarding its short and long-term law enforcement and policy agenda and to put all of its knowledge regarding the pharmaceutical industry and exclusionary bundled discounts and conditional pricing practices to work.

Specifically, given the importance of entry of innovative treatments to the reduction of drug pricing, the FTC should immediately address the anti-competitive rebate wall. It can help tear down this wall and allow new rival drugs open and fair access to the market and consumers access to cost saving treatments. The FTC can do this by immediately opening investigations into suspect exclusionary rebates, multiproduct and indication rebates, and conditional pricing discounts.

If it discovers that the alleged pricing practices are having an anti-competitive, exclusionary effect, the FTC should bring its own litigation in federal court or in front of an administrative law judge to prohibit the conduct. The Pfizer case, in particular, provides the FTC with a legal roadmap to follow in terms of how to draft a complaint that will survive a motion to dismiss. Well-conceived investigations and litigation by the FTC are essential to shaping the law and protecting competition in crucial drug markets.

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[1] Pfizer v. Johnson & Johnson, et al., No. 17-cv-4180 (E.D. Pa August 8, 2018) and Shire v. Allergan, Inc., No. 2:17-cv-7716 (D.N.J. October 2, 2017).

[2] See Aaron Hakim and Joseph S. Ross, Obstacles to the Adoption of Biosimilars for Chronic Diseases, JAMA, vol. 317, no. 21 (June 6, 2017) ("JAMA"). PhRMA Comment to FTC, Docket No. FTC-2018-0048: Competition and Consumer Protection in the 21st Century Hearings, Project Number P181201, August 20, 2018; PhRMA Comment Submitted to HHS Regarding HHS Blueprint to Lower Drug Prices, July 16, 2018, at 13-24.

[3] Pfizer Comment Submitted to HHS Regarding HHS Blueprint to Lower Drug Prices, July 16, 2018, at 41; Biosimilars Council Comment Submitted to HHS Regarding HHS Blueprint to Lower Drug Prices, July 16, 2018, at 4-7; Momenta Pharmaceuticals Comment Submitted to HHS Regarding HHS Blueprint to Lower Drug Prices, July 16, 2018, at 17, 24, 26; Novartis Comment Submitted to HHS Regarding HHS Blueprint to Lower Drug Prices, July 16, 2018 (discussing the need for transparency regarding the impact of rebates paid to PBMs for formulary placement); Eli Lilly & Company Comment Submitted to HHS Regarding HHS Blueprint to Lower Drug Prices, July 16, 2018.

[4] HHS Press Release, Trump Administration Proposes to Lower Drug Costs by Targeting Backdoor Rebates and Encouraging Direct Discounts to Patients, January 31, 2019.

[5] PhRMA Comment Submitted to HHS, April 8, 2019; Mylan Comment Submitted to HHS, April 8, 2019 at 27 ("Formulary conditions on rebates for branded biologic drugs can make coverage of lower priced biosimilars and generics financially disadvantageous for Part D plans"); Eli Lilly Comment Submitted to HHS, April 8, 2019 at 6-9 ("The FTC and/or DOJ should issue guidance regarding the government's position on rebate walls"); Pfizer Comment Submitted to HHS, April 5, 2019 at 4; Alliance for Safe Biological Medicines Letter, April 8, 2019 ("rebate system actually encourages higher prices and impedes rather than expands access to lower priced biosimilars").

[6] Steve Salop, "The Raising Rivals' Cost Foreclosure Paradigm, Conditional Pricing Practices, and the Flawed Incremental Price-Cost Test" (2017). Georgetown Law Faculty Publications and Other Works. 1620. Pfizer v. Johnson & Johnson, et al, No. 17-cv-4180 (E.D. PA August 8, 2018); Shire v. Allergan, Inc., No. 2:17-cv-7716 (D.N.J. October 2, 2017).

[7] Vas Narasimhan, How to Create Cheaper Alternatives to the Most Expensive Drugs, Forbes, April 12, 2018.

[8] Alex M. Azar, Remarks to the Bipartisan Policy Center, February 1, 2019. "Congress has an opportunity to follow through on their calls for transparency, too, by passing our proposal into law immediately and extending it into the commercial drug market."

[9] JAMA, supra note 2.

[10] Id.

[11] Id.

[12] Robin Feldman, Why Prescription Drug Prices Have Skyrocketed?, Washington Post, November 26, 2018.

[13] David Balto, Rebate Walls Should Be Dismantled by FTC's Antitrust Arm, STAT News, December 4, 2018.

[14] Peter Sullivan, Gottlieb: Drug rebates not benefiting sicker patients, The Hill, March 6, 2019;

Fact Sheet: Trump Administration Proposes to Lower Drug Costs by Targeting Backdoor Rebates and Encouraging Direct Discounts to Patients, Department of Health & Human Services, February 6, 2019.

[15] Id.

[16] Id.

[17] American College of Rheumatology, Step Therapy: Instead of Fail first, Put Patients First, available at <https://www.rheumatology.org/Portals/0/Files/Issue-Brief-Step-Therapy.pdf>;

[18] Pfizer Q2 2018 Earnings Call available online at https://s21.q4cdn.com/317678438/files/PFEUSQ_Transcript_2018-07-31.pdf

[19] Remarks by Scott Gottlieb, Advancing Patient Care Through Competition, April 19, 2018.

[20] Id.

[21] Pfizer v. Johnson & Johnson, et al, No. 17-cv-4180 (September 20, 2017).

[22] Compl. at ¶6.

- [23] Id. at ¶¶ 8, 9, 11, 55-79, 98).
- [24] Id. at ¶¶ 71, 123-133.
- [25] Id. at ¶¶ 66, 98.
- [26] Id. at ¶¶ 10, 12, 72, 100, 102, 127.
- [27] Pfizer v. J&J, Civ. No. 17-cv-4180 (E.D. Pa. August 8, 2018).
- [28] Id. at 18-20.
- [29] Id. at 20
- [30] Shire v. Allergan, Inc., No. 2:17-cv-7716 (D.N.J. October 2, 2017).
- [31] Compl. ¶¶ 1, 15, 16, 24, 86, 87, 93, 97, 125, 126, 134, 141, 153, 173, 181
- [32] Compl. ¶ 8, 20, 38.
- [33] Id. at ¶ 6, 40.
- [34] Compl. ¶ 15.
- [35] Shire US, Inc. v. Allergan, Inc., No. 17-cv-7716 (D.N.J. Mar. 22, 2019). The same court also has pending litigation on exclusionary loyalty bundling rebates (Sugartown Pediatrics LLC v. Merck & Co., No. 2:18-cv-01734 (E.D. Pa. April 25, 2018)). In 2012, the District of New Jersey held that allegations of an exclusionary bundling rebates program were sufficient to overcome a motion to dismiss (Castro v. Sanofi, No. 11-cv-7178, 2012 WL 12516572 (D.N.J. Aug. 6, 2012)).
- [36] Shire US, Inc. v. Allergan, Inc., No. 17-cv-7716 (D.N.J. Mar. 22, 2019).
- [37] Id.
- [38] Id.
- [39] 509 U.S. 209 (1993).
- [40] LePage's v. 3M, 324 F.3d 141, 154-155 (3rd Cir. 2003).
- [41] ZF Meritor, LLC v. Eaton Corp., 696 F.3d 254 (3rd Cir. 2012).
- [42] Id. at 269.
- [43] Id. at 269.
- [44] Eisai, Inc. v. Sanofi-Aventis, U.S., LLC, 821 F.3d 394 (3d Cir. 2016).
- [45] Salop, Raising Rivals Costs; Cascade Health Sols. v. PeaceHealth, 515 F.3d 883, 901 (9th Cir. 2008) (holding that Brooke Group price cost test should be applied bundled discounts).

[46] Salop, Raising Rivals Costs.

[47] Salop, Raising Rivals Costs.

[48] Joint FTC and DOJ Workshop To Explore Conditional Pricing Practices available at <https://www.ftc.gov/news-events/events-calendar/2014/06/conditional-pricing-practices-economic-analysis-legal-policy>.