

## Federal Trade Commission Report on Rebate Walls

Congress directed the Federal Trade Commission (FTC) to report to the Committees on Appropriations of the House and Senate regarding the FTC's efforts during the preceding 18 months to address "an increasingly common anticompetitive behavior potentially distorting the U.S. biopharmaceutical market known as rebate walls."<sup>1</sup> Rebate walls refer to a situation in which a dominant pharmaceutical manufacturer uses rebate strategies in its contracts with third party payors to maintain market power, by giving its products preferred status in drug formularies, and to prevent sales of competing products. The Committees urge the FTC to make investigations into drug manufacturers' anticompetitive use of rebate walls an enforcement priority. The Committees also encourage the FTC to coordinate with the Centers for Medicare and Medicaid Services and the Food and Drug Administration (FDA) concerning enforcement and consumer education activities regarding rebate walls.

The FTC has a long history of promoting competition in pharmaceutical markets.<sup>2</sup> Competition among pharmaceutical products can create substantial savings, not only to patients but also to purchasers throughout the health-care system, both public and private. Such competition may occur in various ways, including so-called "brand-on-brand" competition (whether biologic or small molecule drugs), "brand-on-generic," "generic-on-generic," or biosimilar products competing against the originator biologic. Competition often involves manufacturers and payers entering into rebate agreements that provide rebates to payers in exchange for market-share guarantees or preferred formulary placement.

A variety of stakeholders have identified rebate wall issues for the Commission. Confidentiality requirements prevent the Commission from discussing the details of the investigations. However, as has been reported publicly, the Commission is closely attuned to pharmaceutical manufacturer contracting practices, including rebate strategies.<sup>3</sup>

This Report discusses the antitrust analysis of such practices generally and should not be interpreted as reflecting conclusions about any particular matter under investigation. As discussed below, the legality of a given rebate arrangement under the antitrust laws depends on a variety of factual issues present in the particular circumstances.

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<sup>1</sup> House Report 116-456 published in the Congressional Record on Dec. 27, 2020 (at <https://www.congress.gov/116/crpt/hrpt456/CRPT-116hrpt456.pdf>) that accompanied H.R. 7668, Financial Services and General Government Appropriations Bill, 2021.

<sup>2</sup> See Overview of FTC Actions in Pharmaceutical Products and Distribution, [https://www.ftc.gov/system/files/attachments/competition-policy-guidance/20200930\\_overview\\_pharma\\_final.pdf](https://www.ftc.gov/system/files/attachments/competition-policy-guidance/20200930_overview_pharma_final.pdf).

<sup>3</sup> The potential for pharmaceutical rebate agreements to foreclose competition was discussed at the FDA/FTC Workshop on a Competitive Marketplace for Biosimilars, March 9, 2020, <https://www.fda.gov/media/136791/download>, and at the FTC's November 2017 workshop, *Understanding Competition in Prescription Drug Markets: Entry and Supply Chain Dynamics*, [https://www.ftc.gov/system/files/documents/public\\_events/1255653/understanding\\_competition\\_in\\_prescription\\_drug\\_markets\\_workshop\\_slides\\_11-8-17.pdf](https://www.ftc.gov/system/files/documents/public_events/1255653/understanding_competition_in_prescription_drug_markets_workshop_slides_11-8-17.pdf). The FTC has been aware of the issues surrounding rebate practices for many years. See 1999 FTC Bureau of Economics Staff Report, *The Pharmaceutical Industry: A Discussion of Competitive and Antitrust Issues in an Environment of Change*, (Mar. 1999), [https://www.ftc.gov/system/files/documents/reports/pharmaceutical-industry-discussion-competitive-antitrust-issues-environment-change/the\\_pharmaceutical\\_industry\\_-\\_march\\_1999.pdf](https://www.ftc.gov/system/files/documents/reports/pharmaceutical-industry-discussion-competitive-antitrust-issues-environment-change/the_pharmaceutical_industry_-_march_1999.pdf).

## Drug Manufacturer Rebates

Drug company rebates arise in the context of contracts between manufacturers and providers or third-party payers, such as commercial health plans, pharmacy benefit managers (PBMs), and Medicare Part D programs. The vast majority of consumers have insurance that covers some or all of the cost of prescription medications.<sup>4</sup> Payers use “formularies” or medical benefit policies to determine which prescription medications they will cover. Most payers use PBMs to design their formularies for pharmacy benefits under their plan. A drug may be “preferred” or “on formulary,” and there may be “tiers” of preferred medications. Payers may also use a process called “step therapy,” “step edits,” or “fail first,” whereby patients prescribed a certain drug must first try and fail a drug in a higher formulary or benefit tier before the plan will cover the cost of the originally-prescribed drug.<sup>5</sup>

Drug companies use rebates as incentives to have their products included on a formulary or in higher tiers of the formulary.<sup>6</sup> These rebates are after-the-fact discounts calculated as a percentage of the drug’s list price. For drugs that are covered by pharmacy benefits under a plan, drug companies most often pay rebates to PBMs, who may pass through some or all of the rebate to the payers.<sup>7</sup> While their precise form may vary, rebate payments are often conditioned on the drug’s continuing to hold a preferred or exclusive position on a payer’s formulary.

Some industry analysts and academics have observed that rebates can become a “trap” for payers and providers, causing them to make decisions about coverage and utilization for their beneficiaries due to the financial incentives created by the rebate structure.<sup>8</sup> The rebate “trap” occurs because the rebate is conditioned on formulary access or a market share requirement. If a rival drug is granted formulary access, the manufacturer may stop paying rebates (or even “claw back” previously paid rebates), thus forcing the third-party payer to face the full list price of the manufacturer’s drug for any purchases of that manufacturer’s drug. If the third-party payer is unable to switch a sufficient proportion of its covered patients to the lower-priced alternative, then granting a rival drug formulary access is not worth losing the original rebates. Thus payers who wish to make the lower cost medication available may have to continue paying for the original product, without the benefit of rebates, for some portion of covered patients in the short term. This “rebate wall” may give payers strong incentives to block patient access to lower-

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<sup>4</sup> See Kaiser Family Foundation, Health Insurance Coverage of the Total Population (2018), <https://www.kff.org/other/state-indicator/total-population/>.

<sup>5</sup> Nat’l Psoriasis Found., What Is Step Therapy?, <https://www.steptherapy.com/what-is-step-therapy/>; Cigna, Step Therapy Frequently Asked Questions, <https://www.cigna.com/pdf/step-therapy-faqs.pdf>.

<sup>6</sup> Katie Thomas, *Meet the Rebate, the New Villain of High Drug Prices*, N.Y. TIMES (July 27, 2018), <https://www.nytimes.com/2018/07/27/health/rebates-high-drug-prices-trump.html>.

<sup>7</sup> See Adam Fein, *Half Off Sale! Five Major Drugmakers Reveal Vast Gross-to-Net Price Gaps—and Why Rebate Reform Is Still Needed*, DRUG CHANNELS (Sept. 17, 2019), <https://www.drugchannels.net/2019/09/half-off-sale-five-major-drugmakers.html>.

<sup>8</sup> See, e.g., Aaron Hakim and Joseph S. Ross, *Obstacles to the Adoption of Biosimilars for Chronic Diseases*, J. AM. MED. ASS’N, (June 6, 2017), Vol. 317, No. 21, p. 2163.

priced medicines, whereas absent rebates a lower-priced equally effective product would tend to take sales from the higher priced incumbent product.<sup>9</sup>

In this way, some rebates can operate to increase overall drug spending. The cost implications are particularly significant for biologics, given their generally higher costs relative to small molecule drugs. In addition, rebate walls such as those described above may reduce incentives for biotechnology companies to develop new medicines and/or invest in biosimilars, harming competition and the quality of care available to patients.<sup>10</sup>

### **Antitrust Analysis of Drug Company Rebate Practices**

Antitrust concerns relating to pharmaceutical manufacturers rebate practices focus on their potential to create or maintain the market power of an incumbent pharmaceutical product. Depending on the circumstances, rebating strategies may be assessed under Section 1 or Section 2 of the Sherman Act. A *prima facie* claim of anticompetitive conduct under Section 2 requires showing two threshold elements: (1) monopoly power in a relevant antitrust market; and (2) the rebating conduct has foreclosed competition. Section 1 requires an agreement and a showing of market power, not monopoly power.

Potential legal theories that might apply in an antitrust challenge to a rebate wall include exclusive dealing, bundling, and tying. Application of these theories is highly fact-specific. Relevant facts for a plaintiff to establish may include market definition and relative market power, the extent of market foreclosure, contract duration, anticompetitive effects and lack of potential countervailing procompetitive justifications, and a customer's practical ability to terminate agreements. A number of antitrust suits have been brought by private plaintiffs, and

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<sup>9</sup> W. Winegarden, *Tear Down This Wall*, PRI Center for Medical Economics and Innovation 4 (Dec. 2020), [https://www.pacificresearch.org/wp-content/uploads/2020/12/RebateWall\\_F\\_web.pdf](https://www.pacificresearch.org/wp-content/uploads/2020/12/RebateWall_F_web.pdf).

<sup>10</sup> News Release, *Klobuchar, Blumenthal, Cicilline, Jeffries Call on GAO to Study Effects of “Rebate Traps” on Pharmaceutical Prices and Competition* (June 10, 2020), <https://www.klobuchar.senate.gov/public/index.cfm/2020/6/klobuchar-blumenthal-cicilline-jeffries-call-on-government-accountability-office-to-study-effects-of-rebate-traps-on-pharmaceutical-prices-and-competition>.

those ongoing are in the early stages.<sup>11</sup> Recently, a district court dismissed one of these cases on summary judgment.<sup>12</sup>

While the FTC is not currently litigating a rebate wall matter, it is actively litigating three cases in the health-care sector alleging other unlawful exclusionary conduct.<sup>13</sup> In April 2019, the Commission filed an action in federal court charging that health information technology company Surescripts, LLC structured its contracts to lock customers into exclusive arrangements in order to ensure that no competitor could gain a toehold in two related markets in which Surescripts operates.<sup>14</sup> The FTC's complaint alleges that through a web of actual and *de facto* exclusive arrangements and other exclusionary conduct, Surescripts was able to protect its dominant position in two e-prescription markets, to the detriment of consumers. In January 2020, the Commission charged Vyera Pharmaceuticals and two individual defendants with a multifaceted scheme to preserve Vyera's monopoly for the life-saving drug, Daraprim.<sup>15</sup> The Commission's complaint alleges that after Vyera acquired Daraprim and raised the list price from \$17.50 to \$750, the defendants engaged in a variety of tactics to keep generic drug companies from competing with lower-priced generic alternatives. These tactics allegedly included exclusive dealing agreements that kept competitors from accessing a critical ingredient

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*See also* Fed. Tr. Comm'n, *In re Victrex*, C-4586 (complaint Apr. 27, 2016) (consent order barring exclusive supply contracts as well as market-share discounts or retroactive volume discounts), <https://www.ftc.gov/enforcement/cases-proceedings/141-0042/victrex-plc-et-al-matter>.

<sup>11</sup> *See, e.g., Pfizer v. Johnson & Johnson, et al.*, No. 17-cv-4180 (E.D. Pa August 8, 2018); *Pfizer v. Johnson & Johnson*, 333 F. Supp.3d 494 (E.D. Pa. 2018) (holding plaintiffs plausibly alleged unlawful exclusive contracts and bundled rebates); *In re Remicade Antitrust Litig.*, 345 F. Supp. 3d 566 (E.D. Pa. 2018) (holding direct and indirect purchasers pleaded valid federal antitrust claims based on exclusive agreements and bundled rebates); *Shire v. Allergan, Inc.*, No. 2:17-cv-7716 (D.N.J. October 2, 2017); *Shire US, Inc. v. Allergan, Inc.*, 375 F. Supp. 3d 538, 540 (D.N.J. 2019) (holding Shire failed to plausibly allege that Allergan used a combination of anticompetitive bundling and exclusive dealing arrangements to unlawfully coerce Medicare Part D plans to exclude Sanofi's competing product). *See also 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 for pediatric vaccines were sufficient to overcome a motion to dismiss (*Castro v. Sanofi*, No. 2:11-cv-7178, 2012 WL 12516572 (D.N.J. Aug. 6, 2012)).

<sup>12</sup> *Sanofi-Aventis U.S. LLC v. Mylan Inc., et al.*, No. 17-cv-02763 (D. Kan.), 2020 WL 8374137 (Dec. 17, 2020) (finding no triable issue of fact concerning Sanofi's claims that Mylan's rebates related to EpiPens constituted unlawful exclusive dealing).

<sup>13</sup> The Commission has used Section 13(b) of the Federal Trade Commission Act for the last four decades to secure billions of dollars in relief for consumers in a wide variety of cases, including anticompetitive pharmaceutical practices. In the past 5 years alone, for example, the agency has used Section 13(b) to provide almost \$11.2 billion in refunds to consumers victimized by a wide variety of schemes. Section 13(b) has been a critical tool in our enforcement mission. But our enforcement efforts will be far less effective in light of the Supreme Court's decision in *AMG Capital Management, LLC v. FTC*, which held that courts can no longer award refunds to consumers in FTC cases brought under 13(b). For antitrust cases, Section 13(b) was the only authority the Commission had to seek monetary relief for consumers. We respectfully request that Congress act to clarify Section 13(b) of the FTC Act and revive the FTC's ability to enjoin illegal conduct and return to consumers money they have lost.

<sup>14</sup> *FTC v. Surescripts*, No. 1:19-01080 (D.D.C.) (complaint filed April 17, 2019), <https://www.ftc.gov/news-events/pressreleases/2019/04/ftc-charges-surescripts-illegal-monopolization-e-prescription>.

<sup>15</sup> FTC News Release, *FTC and NY Attorney General Charge Vyera Pharmaceuticals, Martin Shkreli and Other Defendants with Anticompetitive Scheme to Protect a List-Price Increase of More Than 4000 Percent for Life-Saving Drug, Daraprim* (Jan. 27, 2020), <https://www.ftc.gov/news-events/press-releases/2020/01/ftc-ny-attorney-general-charge-vyera-pharmaceuticals-martin>.

needed to make generic Daraprim.<sup>16</sup> Finally, in January 2021, the Commission charged Endo Pharmaceuticals Inc. and Amneal Pharmaceuticals, Inc. with unlawfully maintaining Amneal’s monopoly in the sale of oxycodone ER, a long-acting opioid used to treat moderate to severe pain, including cancer pain.<sup>17</sup>

In addition to its law enforcement initiatives, the FTC collaborates with the FDA to promote more competitive markets for pharmaceutical products. The two agencies have a long history of cooperation on such matters. The FTC’s review of pharmaceutical patent settlement agreements submitted under congressional mandate is aided by consultations with the FDA.<sup>18</sup> As of December 2018, those submissions now include agreements between reference product biologic companies and biosimilar manufacturers.<sup>19</sup>

In February 2020, the FTC and the FDA issued a joint statement confirming their intent to strengthen interagency coordination to help “address and deter anticompetitive behavior in the U.S. market for biological products.”<sup>20</sup> In addition to anticompetitive reverse-payment agreements, the agencies seek to address various forms of “gaming” of the regulatory frameworks that govern the sale of biopharmaceutical products, such as abuse of the citizen petition process and of restricted drug distribution programs to obstruct or delay competition. Another issue of joint concern is the use of false or deceptive communications concerning biologics and biosimilars, which can distort decisions made by health care providers and deprive consumers of more cost-effective treatments.

## Conclusion

The Commission 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

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<sup>16</sup> *FTC et al. v. Viera Pharmaceuticals, LLC, et al.*, No. 20-00706 (S.D.N.Y) (complaint filed Jan. 27, 2020; amended complaint filed Apr. 14, 2020), <https://www.ftc.gov/news-events/press-releases/2020/04/six-more-states-join-ftc-nyattorney-generals-case-against-vyera>.

<sup>17</sup> *FTC v. Endo Pharmaceuticals et al.*, No. 1:21-cv-00217 (D.D.C.) (complaint filed Jan. 25, 2021), [https://www.ftc.gov/system/files/documents/cases/redacted\\_complaint\\_0.pdf](https://www.ftc.gov/system/files/documents/cases/redacted_complaint_0.pdf).

<sup>18</sup> Section 1112 of Subtitle B (“Federal Trade Commission Review”) of Title XI of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (21 U.S.C. § 355 note), as amended, does not appear to cover agreements with 505(b)(2) applicants. Settlement agreements concerning 505(b)(2) applications could contain anticompetitive features that the FTC should review.

<sup>19</sup> Section 1112 of Subtitle B (“Federal Trade Commission Review”) of Title XI of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (21 U.S.C. § 355 note), as amended, requires that brand-name drug manufacturers, generic drug applicants, and biosimilar biological product applicants file certain agreements with the Federal Trade Commission and the Department of Justice within 10 business days of execution of the agreement. This requirement became effective on January 7, 2004, and was extended to biological products on October 10, 2018. The FTC has released 14 annual reports; the reports and other information about the FTC’s review of these agreements are available at <https://www.ftc.gov/tips-advice/competition-guidance/industry-guidance/health-care/pharmaceutical-agreement-filings>.

<sup>20</sup> *Joint Statement of the Food & Drug Administration and the Federal Trade Commission Regarding a Collaboration to Advance Competition in the Biologic Marketplace* at 3 (February 3, 2020), [https://www.ftc.gov/system/files/documents/public\\_statements/1565273/v190003fdafctbiologicsstatement.pdf](https://www.ftc.gov/system/files/documents/public_statements/1565273/v190003fdafctbiologicsstatement.pdf).

artificially high or deter innovation, and deny patients access to competing treatments.<sup>21</sup> Outside of case-by-case enforcement, the Acting Chairwoman has announced the creation of a group to consider rulemaking, including competition rules with respect to pharmaceutical industry practices. We look forward to building on previous work with Congress to promote competitive health care markets

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<sup>21</sup> Investigations and any resultant litigation are extremely resource intensive, and it is worth noting that the Commission's competition resources are already stretched extremely thin by a high level of merger filings and our very active litigation docket. Congress has increased the FTC's funding in the past two fiscal years and the agency is profoundly grateful. But these increases have not been enough to keep pace with the demands on the agency.