



Antitrust Implications of HHS Proposal to Limit Manufacturer Rebates

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Thomas R. Barker, JD
Ross Margulies, JD, MPH
Erik Schulwolf, JD

Foley Hoag LLP

I. Introduction

In May 2018, the Department of Health and Human Services (HHS) introduced a “Blueprint” and Request for Information setting forth proposed actions and policies as a means to purportedly help lower prescription drug costs.¹ A major focus of the Blueprint is reform of the existing manufacturer rebate system under which drug manufacturers negotiate rebates and volume discounts with plan sponsors (and their contracted pharmacy benefit managers, or PBMs) in exchange for formulary placement and favorable coverage policies. Several proposed policies in the Blueprint, as well as other policies reportedly under review by the Administration, would result in elimination or restriction of rebates in favor of upfront discounts or fixed prices for brand drugs.

This white paper begins by describing the proposals contained in HHS’ Blueprint, as well as subsequent policy announcements, which would have the direct or practical impact of eliminating or restricting manufacturer rebates to plan sponsors and their PBMs in favor of upfront discounts. We then describe how the current rebate system came about, arising from a 1990s-era antitrust legal settlement between drug manufacturers and pharmacies.

As we will explain below, while the settlement agreement between the parties has long since expired, the antitrust laws that led to that settlement are still very much alive and well. As a result, it is our contention that, as the Administration considers policies which rely in whole or in part on upfront discounts or fixed prices, it must carefully consider how current antitrust laws may prevent or deter discounts that are at least as large as the rebates in today’s drug supply chain. Absent such careful consideration, including revisions to existing antitrust laws by Congress which have the current practical and legal effect of limiting and/or reducing the amount of upfront discounts offered by manufacturers, any efforts to modify the current rebate system may result in increased net drug prices, in contravention of the goals of the Administration and the HHS Blueprint.

II. The Trump Administration’s “Fixed Price Discounting” Proposal

On May 16, 2018, HHS released a policy statement and request for information (RFI) entitled, “HHS Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs.”² Among dozens of other policy considerations, HHS argues in the Blueprint that higher rebates in Federal health care programs may be causing higher list prices in public programs (and also increasing the

¹ 83 Fed. Reg. 22,692 (May 16, 2018).

² Id.

prices paid by consumers, employers, and commercial insurers).³ In response to this concern, HHS asks what the Centers for Medicare & Medicaid Services (CMS) should do to restrict or reduce the use of rebates. HHS seeks comment on whether Medicare Part D should prohibit the use of rebates in contracts between Part D plan sponsors and drug manufacturers, and instead require these contracts to be based only on a “fixed price discount” for a drug over the contract term. HHS also asks what incentives or regulatory changes (e.g., removing the discount safe harbor) could restrict the use of rebates and reduce the effect of rebates on list prices. Finally, HHS seeks comment on the impact and unintended consequences of a policy restricting the use of rebates on the behavior of drug manufacturers, PBMs, and insurers, and how it may impact formulary design, premium rates, and the overall structure of the Part D benefit. Public comments on the Blueprint were due July 16, 2018.

Echoing the policy concerns in the Blueprint, senior Administration officials have also publicly expressed concerns about the use of rebates in Federal health care programs and suggested alternative solutions centering largely on a proposal which would subject some or all rebates to Federal anti-kickback statute scrutiny.⁴ For example, on May 3, 2018 FDA Commissioner Scott Gottlieb in an address to the 2018 FDLI Annual Conference noted:

“To take one example, one of the dynamics I’ve talked about before that’s driving higher and higher list prices, is the system of rebates between payers and manufacturers. *And so what if we took on this system directly, by having the federal government reexamine the current safe harbor for drug rebates under the Anti-Kickback Statute?* Such a step could

³ *Id.* at 22,698 (Should Medicare Part D prohibit the use of rebates in contracts between Part D plan sponsors and drug manufacturers, and require these contracts to be based only on a fixed price for a drug over the contract term? What incentives or regulatory changes (e.g., removing the discount safe harbor) could restrict the use of rebates and reduce the effect of rebates on list prices? How would this affect the behavior of drug manufacturers, PBMs, and insurers?). Ironically, the Blueprint was released merely days before the Medicare Trustees Report was published, in which the Trustees credited the current rebate system with lower Part D premiums. *See* 2018 Annual Report of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Trust Funds at 34 (June 5, 2018).

⁴ The federal anti-kickback statute, 42 U.S.C. § 1320a-7b, prohibits the exchange (or offer to exchange), of anything of value, in an effort to induce (or reward) the referral of federal health care program business. However, the statute also exempts certain conduct from kickback scrutiny, including “a discount or other reduction in price...”, as well as “any payment practice specified by the Secretary in regulations...” *See* § 1320a-7b(b)(3). By regulation, CMS has adopted dozens of “regulatory safe harbors,” including a safe harbor mirroring the statutory exception for discounts and explicitly referencing rebates as exempt from kickback scrutiny. *See* 42 C.F.R. § 1001.952(h). Absent safe harbor protection, a rebate paid by a manufacture to a plan sponsor could be viewed as a “kickback” to the extent it is the intent of the manufacturer, in making payments to the plan, to cause additional units of its drugs to be purchased and reimbursed by federal health care programs.

help restore some semblance of reality to the relationship between list and negotiated prices, and thereby boost affordability and competition.”⁵

In remarks to the American Enterprise Institute on May 16, 2018, Secretary of HHS Alex Azar explained this policy further, noting:

“We would welcome the PBM industry coming forth with broader proposals for moving away from today’s system, including a plan for implementation with the pharmaceutical industry. But we also have the administrative power to end this system ourselves—to eliminate rebates and forbid remuneration from pharmaceutical companies, align interests, and end the corrupt bargain that keeps driving list prices skyward.”⁶

In his recent comments before the Senate Health, Education, Labor & Pensions (HELP) Committee, Secretary Azar went further, noting: “Rebates are allowed under an exception to the Anti-Kickback Statute, and that’s an exception that we believe by regulation we could modify.”⁷

On July 18, 2018, the Office of Management and Budget (OMB) received a proposed rule from HHS entitled, “Removal of Safe Harbor Protection for Rebates to Plans or PBMs Involving Prescription Pharmaceuticals and Creation of New Safe Harbor Protection.” While the contents of the rule are not yet publicly available, a reasonable reading based on the title of the proposed rule suggests that HHS intends to remove the existing regulatory safe harbor protection for some or all PBM rebates, subjecting them to anti-kickback statute scrutiny. As a consequence of such a policy, manufacturers would likely be driven to move toward a system of upfront discounts in lieu of currently administered retrospective rebates.

As we discuss below, the current rebate paradigm is the result of existing antitrust laws and a 1990s era legal settlement which effectively foreclosed the use of upfront discounts. As HHS considers whether to propose and adopt any policy which restricts or prohibits rebates, it should carefully consider whether or not a system based on discounts, instead of rebates, is viable given the significant legal impediments.

⁵ Speech by Scott Gottlieb, M.D., Commissioner of Food and Drugs. Keynote Address at the 2018 Food and Drug Law Institute Annual Conference, Washington, DC (May 3, 2018) (Emphasis added).

⁶ Speech by Alex M. Azar II, Secretary of Health and Human Services. Address to AEI, Brookings USC Schaeffer, PBGH, and other policy and stakeholder groups, Washington, DC (May 16, 2018)

⁷ Testimony of HHS Secretary Alex Azar before the Senate Health, Education, Labor and Pensions Committee (June 12, 2018).

III. 1990s Litigation Challenged Upfront Discounts

Under current practice, most manufacturers of branded drugs provide retrospective rebates to plan sponsors and their contracted PBMs based on the plans' members utilizing certain drugs at amounts that exceed certain market share metrics. As alluded to by now-FDA Commissioner Scott Gottlieb in a 2016 *Forbes* article,⁸ the current rebate system in which some or all rebated amounts are correlated/conditioned on the amount of market share that a PBM can deliver dates back to the early 1990s.⁹ Before that time, most manufacturers offered either upfront discounts on their products in exchange for greater volume and formulary access or else rebates *not* conditioned on volume – much like the type of upfront pricing now touted by current Administration officials as a “solution” to rising drug prices.

In 1994, a lawsuit (designated “*In re Brand Name Prescription Drug Antitrust Litigation*”) was filed by hundreds of retail drugstore pharmacies and was later certified as a class-action suit containing “tens of thousands of retail pharmacies, ranging in size from individual, small pharmacies to large, multi-state chains” against many, if not most, of the major brand manufacturers in the market at that time.¹⁰ At the heart of the lawsuit were two antitrust laws – the Sherman Antitrust Act, 15 U.S.C. § 1, and the Robinson-Patman Act, 15 U.S.C. § 13(a).

The Sherman Act, for its part, prohibits any conduct “in restraint of trade or commerce...”¹¹ Courts have broadly interpreted the purpose of the Sherman Act as to promote independent conduct and to “preserv[e] free and unfettered competition as the rule of trade” so that “the unrestrained interaction of competitive forces will yield the best allocation of our economic

⁸ Note that some observers dispute the claim, as made by Commissioner Gottlieb, that rebating as a practice originated in the mid-1990s litigation. What appears to be accurate is that while the practice of rebating predated this litigation, the now commonplace practice of rebates conditioned on market share/volume arose directly from this litigation, in an attempt to overcome barriers perceived to be imposed by anti-trust laws.

⁹ Scott Gottlieb, “How Congress Can Make Drug Pricing More Rational,” *Forbes* (September 12, 2016). *See also* Health Care Financing Admin., *Study of Pharmaceutical Benefit Management Industry*, at 24 (June 2001) (“By 1994, the PBM business began to mature, and manufacturers were generally not recognizing the anticipated value from their contracting practices, despite the dramatic increases in total rebate payments. At the same time, pricing litigation placed manufacturers under scrutiny and caused them to become more discerning about conditions under which rebates would be paid. As a result, manufacturers made a fundamental change in their approach to contracting with PBMs. In general, rebate pricing criteria were changed so that PBMs would have to deliver increases in market share before all or most of the rebate would be paid.”)

¹⁰ *See generally In re Brand Name Prescription Drugs Antitrust Litig.*, No. 94-C-897, 1996 Dist. WL 167350, at *10 (N.D. Ill. Apr. 4, 1996), *opinion modified on reconsideration*, No. 94 C 897, 1996 WL 351178 (N.D. Ill. June 24, 1996), and *rev'd*, 123 F.3d 599 (7th Cir. 1997).

¹¹ *See* 15 U.S.C. § 1 *et seq.*

resource, the lowest prices, the highest quality and the greatest material progress...”¹² The Robinson-Patman Act similarly prohibits uncompetitive practices, but does so by prohibiting the specific practice of price discrimination. In particular, the Robinson-Patman Act makes it unlawful for a seller to differentially price a good or service based solely on the status of the buyer or purchaser where such an act prevents or inhibits competition.¹³ In other words, the Robinson-Patman act looks unfavorably upon certain price differentials that have the tendency to reduce, rather than promote, competition. The rationale supporting the illegality of such a practice is that price discrimination may give favored customers an edge in the market that has nothing to do with their superior efficiency.

In the lawsuit, the pharmacies argued that drug manufacturers conspired together in violation of the Sherman and Robinson-Patman Acts to refuse to offer the plaintiff pharmacies the same discounts on drug purchases that were offered to other purchasers, such as hospitals and health plans. A sub-set of the original plaintiffs opted not to join the class but, nevertheless, asserted individual price discrimination claims against the brand drug manufacturers alleging violations of both the Sherman and Robinson-Patman Acts.

Eventually, many of the defendant manufacturers settled with the plaintiff retailers and, while not all of the specific terms of the settlement agreement are public, the judge presiding over the case approved an amended settlement agreement on June 21, 1996 that sufficiently addressed the plaintiff pharmacies’ concerns about the pricing conduct of the defendant drug manufacturers.¹⁴ In approving the amended settlement agreement, the Court articulated “two commitments which it felt to be appropriate on the part of the settling defendants: (1) That a manufacturer shall not refuse to discount its goods based solely on the status of the buying entity; and (2) To the extent that retail pharmacies and retail buying groups can demonstrate an ability to affect market share in the same or similar manner in which managed care entities are able, retailers will be entitled to the same types of discounts given to managed care entities for this reason.”¹⁵ The Court indicated that while “the language propounded by the amendment does not mirror precisely the language articulated by the court we believe that the amendment sufficiently addresses our stated concerns and in fact represents a firm commitment on the part of the settling defendants.”¹⁶

¹² Northern Pacific Rv. Co. v. United States, 356 U.S. 1, 4 (1958). *See also* Connerweld Corp. v. Independence Tube Corp., 467 U.S. 752, 767-68 (1984).

¹³ See 15 U.S.C. § 13(a).

¹⁴ In re: Brand Name Prescription Drugs Antitrust Litigation, No. 94-C-897, 1996 U.S. Dist. LEXIS 8817 at *10 (N.D. Ill. June 21, 1996).

¹⁵ Id. at 9-10.

¹⁶ Id. at 9-11.

The current retrospective rebating practice in which rebated amounts are conditioned on a PBM moving a certain amount of volume thus became commonplace after the settlement as a way to allow manufacturers to differentially price their products *without* violating applicable antitrust laws. In particular, the practice of retrospective rebating was designed to ensure that even retail pharmacies (as opposed to only health plans, PBMs, etc.) could access beneficial discounts previously not offered to them. In order to settle the litigation, manufacturers agreed that “retail pharmacies and buying groups *that are able to demonstrate an ability to affect market share* will be entitled to discounts based on that ability, to the same extent that managed care organizations would get such discounts.”¹⁷

IV. In Response to Settlement Agreement, A New Rebate Paradigm Created

In re Brand Name Prescription Drugs Antitrust Litigation led drug manufacturers to change their approach to pricing. Manufacturers moved away from upfront, volume-based discounts (which, under antitrust law and the settlement agreement, generally needed to be extended to all purchasers on the same terms) and rebates not conditioned on volume, and in their place, manufacturers shifted to the use of retrospective rebates based on a PBM’s ability to affect market share. As noted above, while the Robinson-Patman Act prohibits *some* differential pricing, it does not prohibit *all* price differentials. In particular, section 2(b) of the Robinson-Patman Act permits the use of price differentials to meet competition from sellers which are offering discounts to specific customers.¹⁸ In other words, while a seller cannot offer differential pricing for *no reason*, it may do so if there are real, functional differences among purchasers.

Unlike an upfront discount, a rebate gives a health plan or other purchaser the ability to first demonstrate the ability to move market share, and only then receive a discount on the price offered. Thus, to incent manufacturers to lower prices, and to avoid antitrust pitfalls, payers acting on behalf of government and commercial plans needed to wait for price reductions after pharmacy dispensing and after the manufacturers verified that the payers met volume or share requirements.

Before his appointment as FDA Commissioner, Scott Gottlieb explained this change in testimony before the Senate. His testimony addressed the question: “Why, in other words, does the discounting in the drug space take the form of rebates paid to pharmacy benefit managers

¹⁷ Testimony of Sarah F. Jaggard, Director of Health Services Quality and Public Health before the House of Representatives Subcommittee on Oversight and Investigations Committee on Commerce (Sept. 19, 1996) (Emphasis added).

¹⁸ 15 U.S.C. § 13(b). *See also Texaco Inc. v. Hasbrouck*, 496 U.S. 543, 562 (1990) (permitting price differentials based on the real functional differences among purchasers).

through a convoluted system on the retrospective of the transaction, rather than an upfront discount on the drugs?”¹⁹ Scott Gottlieb testified that “[i]t all stems from litigation in the late 1990s. . . . To get around this outcome, the drug makers moved away from offering discounts and toward today’s model of rebates.”²⁰

V. Legislative Change Needed to Allow Discounts if Manufacturers Cannot Offer Rebates

Absent Congressional action, manufacturers would be likely unwilling or unable to offer the same level of price concessions through an upfront discounting system that they do currently by way of volume-based rebates. FDA Commissioner Scott Gottlieb and others have recognized the importance of legislative change to ensure manufacturers will provide upfront discounts.²¹ We note at the outset, even with such legislative action, Congress and the agency would likely need to solve for a number of other barriers, including the significant costs associated with a change in the way in which price reductions (through rebates) are currently administered across the drug supply chain.

Necessary legal change could be accomplished, in part, by an amendment to the Robinson-Patman Act. In order to achieve the same level of price concessions that are achieved today through retrospective rebates, manufacturers would need to be allowed, at the front-end, to price differently based on differences in volume or share commitments. If Congress agreed (and assuming a number of other variables fell into place, including industry cooperation), this pricing approach, when done at the front-end, could be exempt from Robinson-Patman Act scrutiny.²²

¹⁹ S. Gottlieb, Resident Fellow at American Enterprise Institute, Statement before the Senate Comm. on Health, Education, Labor and Pensions, *EpiPen Price Increases, How Regulatory Barriers Inhibit Pharmaceutical Competition* (Oct. 7, 2016), at 11.

²⁰ Gottlieb, , *supra* n. 8. (“It’s the outcome of a two-decade old dispute that forced drug makers to try and conceal just how much they discounted off the medicines that they were selling to health plans. . . . To work around the litigation, and the settlement they struck with the pharmacies, drug makers came up with a rebate scheme rather than offering discounts up front.”).

²¹ Gottlieb, *supra* n. 18 (“Could Congress legislate to make it legal for drug makers to engage in price discrimination based on purchaser, offering discounts to one channel and not to another, so long as the drug makers were not conspiring to offer similar discounts? The answer, probably, is yes.”); *See also* Gottlieb, *supra* n. 8. (“Addressing the precedent set by that court ruling . . . could provide policy makers with a simple way to improve the transparency, competitiveness, and affordability of how drugs are priced and sold.”).

²² While the plaintiffs in *In re: Brand Name Prescription Drugs Antitrust Litigation* alleged violations of the Sherman Act, in addition to the Robinson-Patman Act, we believe it is less of a barrier and less relevant to the current policy proposals put forth by the Administration. In particular, while the Robinson-Patman Act is concerned

Congress has several options in this regard. First, Congress could entirely repeal the Robinson-Patman Act, including section 2(a) which prohibits a seller from charging two competing buyers two different prices for the same commodity. Indeed, previous Administrations have recommended as such, recognizing the negative impact the Robinson-Patman Act has on competition generally, and price reductions and discounts specifically. Repeal or overhaul of the Robinson-Patman Act has been recommended in at least four major reports since its enactment in 1936: in 1955,²³ 1969,²⁴ 1977,²⁵ and most recently in December 2007.²⁶ In 1977, directed by then President Gerald Ford, the Department of Justice conducted an in-depth study of the repeal of the Robinson-Patman Act, finding that “the overall effect of Robinson-Patman is to instill extreme pricing caution in sellers and buyers,” and “the Robinson-Patman Act discourages pricing flexibility on the part of sellers and thus leads to higher prices.”²⁷ The record is thus also replete with evidence that in the absence of a repeal of the Robinson-Patman Act, upfront discounts in lieu of retrospective volume-based rebates will leader to lower overall cost savings (and higher, overall, drug prices).

Two other amendments could leave the law in place without gutting all of the protections. First, Congress could codify into law a “cost justification” defense to the Robinson-Patman Act which would allow manufacturers to offer differential pricing if justified by cost savings. As an alternative, Congress could codify a “functional discount” doctrine, recognizing through statute that sometimes purchasers do more than just buy product from a seller (i.e. recognizing the added value that PBMs bring to the marketplace.)

with a company’s unilateral pricing decisions, including the use of discriminatory pricing, the Sherman Act generally prohibits only *concerted* action among competitors in the setting of prices.

²³ Attorney Generals National Commission to Study the Antitrust Laws, Report 155-221 (1995).

²⁴ Phil C. Neal et al., Task Force on Antitrust Policy, Report of the White House Task Force on Antitrust Policy, Antitrust Law and Economic Review., Winter 1968–69, at 11, 13

²⁵ Department of Justice, Report on the Robinson-Patman Act 6-7 (1977).

²⁶ Antitrust Modernization Commission, Report and Recommendations, i, iii (2007).

²⁷ Department of Justice, Report on the Robinson-Patman Act, at 8 (1977). See also Remarks at the Annual Meeting of the Chamber of Commerce of the United States, 1975 Pub. Papers 598, 603 (Apr. 28, 1975) (“The Robinson-Patman Act is a leading example of [a law] which restrain[s] competition and den[ies] buyers substantial savings It discourages both large and small firms from cutting prices, and it also makes it harder for them to expand into new markets and to pass on to customers the cost savings on large orders.”)

VI. Conclusion

As the Administration and HHS consider policy proposals that could result in lower drug prices, including proposals that could eliminate or restrict rebates, the 1990s antitrust litigation should act as a cautionary tale. While the settlement agreement in *In re Brand Name Prescription Drugs Antitrust Litigation* expired in 1999 (three years after its signing), the underlying antitrust laws that ultimately led to the current retrospective, volume-based rebate system remain in effect. As currently worded, the Sherman Act and the Robinson-Patman Act are barriers to any system that relies on upfront or fixed prices, as manufacturers would be forced to offer the same or similar discounts to a wide variety of purchasers. Any system that forces equity in price concessions would necessarily reduce the level of overall price concessions as competition would be discouraged.²⁸ If, in fact, the Administration seeks to lower overall net drug prices, it should ensure it is not both depriving payers of a critical tool (rebates) and replacing it with one (upfront discounts) that faces significant legal obstacles.

²⁸ Indeed, the Court in *In re Brand Name Prescription Drugs Antitrust Litigation*, recognized that the imposition of a “one price policy” throughout the pharmaceutical industry “would discourage competition, not enhance it.” No. 94 C 897, 1996 WL 167350, at 15 (N.D. Ill. Apr. 4, 1996).