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Antitrust Implications of HHS' Proposed Rule to Limit Manufacturer Rebates

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I. Introduction

In February of 2019, the Department of Health and Human Services' Office of Inspector General (HHS-OIG) issued a Proposed Rule that, if adopted, would upend the current prescription drug rebate system.[1] According to HHS-OIG, the current rebate system is a significant cause of high drug prices. The agency argues in the Federal Register notice accompanying the rule that the current system harms patients, lacks transparency, and is detrimental to state and Federal government health care programs.

The major focus of the Proposed Rule is disrupting the existing manufacturer rebate system under which drug manufacturers negotiate rebates with plan sponsors (and their contracted pharmacy benefit managers, or PBMs) in exchange for formulary placement, development of a pharmacy network, and favorable coverage policies. The Proposed Rule, if adopted, would result in an elimination or restriction of rebates in favor of upfront discounts or fixed prices for brand drugs.[2] It would accomplish this in two ways: first, the Proposed Rule would remove safe harbor protection from any discount or remuneration paid from a manufacturer to a Medicare Part D or Medicaid managed care plan unless the remuneration or discount was mandated by law. Second, the Proposed Rule would add two new safe harbors: one protecting price reductions that are fully passed through at the point-of-sale, and a second protecting fixed fees paid from manufacturers to pharmacy benefit managers (PBMs) for services that meet specified criteria.

This white paper begins by describing the proposals contained in HHS-OIG's Proposed Rule, which would have the direct or practical impact of eliminating or restricting retrospective manufacturer rebates to plan sponsors and their PBMs in favor of upfront discounts. We then describe how the current rebate system came about, arising in part from a 1990s-era antitrust legal settlement between drug manufacturers, wholesalers, and pharmacies that continued through into 2015.

As we will explain below, while the settlement agreement between the parties has long since expired, and the litigation has now concluded, the antitrust laws that led to that settlement are still very much alive and well. A 2015 decision by the United States Court of Appeals for the

[1] 84 Fed. Reg. 2,340 (Feb. 6, 2019).

[2] Throughout this white paper, you will see us use the term "discount" to refer to those upfront payments in the drug supply chain made by manufacturers to PBMs and/or health plans in exchange for volume commitments, favorable coverage policies, and more. We use the term "rebate" to refer to those back-end or retrospective payments made by manufacturers for a similar set of considerations. We note that for purposes of analysis under the Robinson-Patman Act, discounts and rebates are generally treated as one and the same. However, it is the contention of the authors that rebates in the drug supply chain, unlike discounts, provide manufacturers with greater flexibility to incent procompetitive conduct, including the ability to recognize the movement of "market share" through retrospective payments.

Second Circuit that finally ended the decades-long antitrust litigation referred to above does not ameliorate those concerns.

As a result, it is our contention that, as the Administration considers policies that rely in whole or in part on upfront discounts, it must carefully consider how current antitrust laws may prevent or deter discounts that are at least as large as the discounts in today's drug supply chain. Absent such careful consideration, including revisions to existing antitrust laws by Congress that 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 Proposed Rule.

II. The Trump Administration's Proposal to Limit Drug Rebates

The release of the Proposed Rule is the culmination of a policy debate that has been simmering for nearly a year on how to address rising drug prices, and the cost borne by patients and government health care programs.

By way of background, 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."[3] Among dozens of other policy considerations announced at that time, HHS argued in the Blueprint that the current rebate system in Federal health care programs may be incentivizing higher list prices in those programs (and also increasing the prices paid by consumers, employers, and commercial insurers).[4] In response to this concern, HHS asked what the agency should do to restrict or reduce the use of rebates. Among other policy ideas floated, HHS asked what incentives or regulatory changes (e.g., removing a regulatory safe harbor that shields the current rebate system from liability under the anti-kickback statute) could restrict the use of rebates and reduce the effect of rebates on list prices. [5]

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[3] 83 Fed. Reg. 22,692 (May 16, 2018).

[4] 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).

[5] 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, the OIG has adopted dozens of "regulatory safe harbors," including a safe harbor mirroring the statutory exception for

Echoing the policy concerns in the Blueprint, senior Administration officials have also publicly expressed concerns over the past year about the use of rebates in state and Federal health care programs and suggested alternative solutions centering largely on a proposal that would subject some or all rebates to Federal anti-kickback statute scrutiny. For example, on May 3, 2018 FDA Commissioner Scott Gottlieb in an address to the 2018 Food and Drug Law Institute 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 help restore some semblance of reality to the relationship between list and negotiated prices, and thereby boost affordability and competition."[6]

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."[7]

In his comments before the Senate Health, Education, Labor & Pensions (HELP) Committee last spring, 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."[8]

The Proposed Rule reflects these policy proposals. If the Proposed Rule were adopted in final form, manufacturers would likely be driven to move toward a system of upfront discounts in lieu

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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 manufacturer 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.

[6] 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).

[7] 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).

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

of currently administered retrospective rebates. As HHS considers comments on the Proposed Rule, it should carefully consider whether, in the context of current antitrust laws, manufacturers will negotiate as large as discounts as they do currently under the existing rebate-based system.

III. 1990s Litigation Challenged Upfront Discounts

As discussed above, 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 meet or exceed certain market share metrics. As alluded to by now-FDA Commissioner Scott Gottlieb in a 2016 Forbes article,[9] 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.[10] Before that time, most manufacturers offered upfront discounts on their products in exchange for greater volume – much like the type of upfront pricing now set forth in the Proposed Rule as a "solution" to rising drug prices.

In 1994, a lawsuit (designated "In re Brand Name Prescription Drug Antitrust Litigation") challenged that system. The 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 and wholesalers in the market at that time. [11] 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…"[12] Courts have broadly interpreted the purpose of the Sherman Act as "preserving free and

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[9] Note that some observers dispute the claim, as made by Commissioner Gottlieb, that rebating as a practice originated at around the time of 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 arose directly from this litigation, in an attempt to overcome barriers perceived to be imposed by antitrust laws.

[10] 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.")

[11] 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).

[12] See 15 U.S.C. § 1 et seq.

unfettered competition as the rule of trade" so that "the unrestrained interaction of competitive forces will yield the best allocation of our economic resource, the lowest prices, the highest quality and the greatest material progress…."[13]

While the Sherman Act protects *competition*, the Robinson-Patman Act instead protects *competitors* by prohibiting the specific practice of price discrimination. In particular, the Robinson-Patman Act requires that each purchaser be given an "equal opportunity" by the seller to receive the benefit of higher or lower prices.[14] By enacting the Robinson-Patman Act, "Congress sought to target the perceived harm to competition occasioned by powerful buyers, rather than sellers."[15]

In the 1994 lawsuit, the pharmacies argued, in part, that drug manufacturers and their wholesale partners violated the Robinson-Patman Act by refusing 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 concerns of the objecting class members about the pricing conduct of the defendant drug manufacturers.[16] 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."[17] 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

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[13] 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).

[14] See 15 U.S.C. § 13(a). See also George Haug Co. v. Rolls Royce Motor Cars, 148 F.3d 136 (2nd Cir. 1998).

[15] Volvo Trucks N. Am., Inc. v. Reeder-Simco GMC, Inc., 546 U.S. 164, 175 (2006).

[16] 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).

[17] Id. at 9-10.

addresses our stated concerns and in fact represents a firm commitment on the part of the settling defendants."[18]

The current retrospective rebating practice in which rebated amounts are conditioned on a PBM moving a certain amount of market share 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 also access beneficial discounts previously not offered to them if they are able to similarly affect market share. 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."[19]

Note that not all plaintiff pharmacies agreed to participate in the settlement. As a result, the litigation continued for these "opt-out" pharmacies, and lasted another 20 years. In 2015, in *Cash and Henderson Drugs, Inc. v. Johnson and Johnson*, 799 F.3d 202 (2nd Cir. 2015), the United States Court of Appeals for the Second Circuit addressed the contentions of the non-settling pharmacies. In a narrow ruling, the Second Circuit concluded that the pharmacies had failed to carry their burden of proof to show competitive injury. Importantly, however, the Court did not thereby sanction the practice of differential discounts; it merely concluded that in this instance, the pharmacies had not met their legal burden to demonstrate harm to competition.[20]

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[18] Id. at 9-11.

[19] Testimony of Sarah F. Jaggar, 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).

[20] The pharmacies opted to prove injury through what the court referred to as an "elaborate matching process" under which the pharmacies would attempt to identify customers they had lost to the favored purchasers through a complex sampling process. Notably, the parties agreed at the conclusion of the matching process, but prior to seeing results, that the results would account for the "universe" of potential lost customers. Using this matching process and in contrast with what the pharmacies had anticipated, the sample produced through the matching process showed few lost customers. Because the parties had stipulated that the matching process would show the universe of lost customers, the pharmacies were unable to introduce additional evidence of injury or lost customers.

Cash & Henderson Drugs, Inc. thus stands for the narrow proposition that a group of opt-out pharmacies from the original In re Brand Name Prescription Drugs case were unable to show competitive injury through one method of determining lost sales. The case does not relieve sellers who provide differential discounts from scrutiny under the Robinson-Patman Act, nor does it ultimately settle whether or not the pharmacies would have been able to show injury if they had used a different process to determine lost sales. Going forward, litigants under the Robinson-Patman Act will likely just refuse to stipulate to the specific type of evidence, allowing greater flexibility in showing injury. Cash & Henderson Drugs, Inc. does not alter the underlying claim that upfront discounts to some purchases, and not to others, can implicate the Robinson-Patman Act.

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

The *In re Brand Name Prescription Drugs Antitrust Litigation* led drug manufacturers to change their approach to pricing. Manufacturers moved further away from upfront, volume-based discounts and rebates (which, under antitrust law and the settlement agreement, generally needed to be extended to all purchasers on the same terms), and in their place, manufacturers shifted to the use of retrospective rebates based on a PBM's or payer's ability to affect market share. As noted above, while the Robinson-Patman Act prohibits *some* differential pricing, it does not prohibit *all* differential pricing. [21] In particular, while volume-based pricing on its own may implicate the Robinson-Patman Act because the discounts are not practically available to small purchasers,[22] discounts based on market-share "theoretically level the playing field by allowing competing purchasers of like commodities to participate on equal terms, regardless of size, because such discounts depend not on volume purchases, but on the percentage of purchases of a particular category of products."[23] Thus, following the 1996 settlement and in an effort to avoid violating the Robinson-Patman Act, manufacturers moved further toward a rebate-based system in which purchasers capable of demonstrating the ability to move market share were rewarded with greater rebates.

Unlike an upfront discount awarded to all purchasers, a rebate gives a health plan or other purchaser the opportunity to first demonstrate the ability to move market share, and only then receive a discount (in the form of a retrospective rebate, after market share is shown to be affected) on the price offered. Thus, to avoid antitrust pitfalls, manufacturers use the rebate system to incent payers and their contracted PBMs to engage in a variety of behaviors (e.g., formulary creation, implementation of utilization management techniques) that increase the sales of the manufacturers' drugs while also lowering the ultimate price paid by the consumer (whether through reduced cost-sharing or lower premiums). Today, the rebate has become the primary vehicle in which manufacturers and purchasers negotiate discounts on drugs.

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[21] 15 U.S.C. § 13(b). See also Texaco Inc., v. Hasbrouck. 496 U.S. 543, 562 (1990) (permitting price differentials based on the functional differences among purchasers).

[22] See FTC v. Morton Salt Co., 334 U.S. 37, 42 (1948) (deeming a volume discount program to be illegal under the circumstances because the manufacturer set the minimum purchase requirement so high that it was impossible for small buyers to obtain the discounts received by large buyers.)

[23] Smith Wholesale Co. v. R.J. Reynolds Tobacco Co., 477 F.3d 854, 864-865 (6th Cir. 2007) ("There is a dearth of precedent addressing the legality of market-share discount programs under the Act; heretofore, legal challenges to secondary-line pricing practices under § 13(a) have arisen in the original context contemplated by the Act -- discriminatory pricing arising from standard quantity discounts.")

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

Absent Congressional action, manufacturers would likely be unwilling or unable to offer the same level of price concessions through an upfront discounting system (as suggested in the Proposed Rule) that they do currently by way of market share-based rebates. FDA Commissioner Scott Gottlieb and others have recognized the importance of legislative change to ensure manufacturers will provide upfront discounts.[24] 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, or full out repeal of, the Robinson-Patman Act. In order to incentivize the same level of price concessions that are achieved today through retrospective rebates recognizing movements in market share, manufacturers would need to be allowed, at the front-end, to price differently without the risk of a Robinson-Patman Act violation. 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.

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,[25] 1969,[26] 1977,[27] and most recently in December 2007.[28] In 1977, 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

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[24] Gottlieb, supra n. 20 ("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.").

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

[26] 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.

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

[28] Antitrust Modernization Commission, Report and Recommendations, i, iii (2007).

buyers," and "the Robinson-Patman Act discourages pricing flexibility on the part of sellers and thus leads to higher prices."[29] The record is replete with evidence that, in the absence of a repeal of the Robinson-Patman Act, upfront discounts in lieu of rebates will leader to lower overall cost savings (and higher, overall, drug prices).

VI. Conclusion

As the Administration and HHS consider policy proposals that could result in lower drug prices, including the current Proposed Rule that would 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, rebate system which rewards market share movement remain in effect. The decision by the Second Circuit (*Cash and Henderson Drugs*) has not affected the landscape.

As currently worded, the Robinson-Patman Act is potentially implicated where a seller offers differential discounts or rebates to competing purchasers. For more than twenty years now, manufacturers, wholesalers, payers, and PBMs have operated within a system of differential rebates which has mitigated risk under the Robinson-Patman Act. Unlike upfront discounts, rebates better enable manufacturers to reward buyers for moving market share and thus encourage deeper price concessions and greater competition in the marketplace. 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 is less likely to incent competitive behavior.

[29] 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.")