

## **Antitrust Considerations of Proposals to Limit Rebates**

### **I. Introduction**

In May 2018, the Department of Health and Human Services (HHS) introduced a policy Blueprint setting forth actions and proposed policies to help lower prescription drug costs. A major focus of the Blueprint is reform of the rebate system. Several proposed policies would result in elimination of rebates in favor of upfront discounts for brand drugs.

Policy reforms that incent brand drug manufacturers to lower prices are needed. Lower brand drug prices will make health insurance more affordable for employers and individuals, reduce consumer spending, and enhance patient access to needed medications. The Administration should be applauded for exploring a range of policies to address the problem of high brand drug pricing.

But some of the proposed changes to the rebate system may have the unintended consequence of higher brand drug prices – potentially much higher. Antitrust precedent is likely to impede a shift from rebates to upfront discounts. For years, brand drug manufacturers have refused to provide upfront discounts based on this antitrust precedent, and instead have required use of rebates. Barring or restricting rebates without addressing this antitrust precedent could lead to substantial consumer and patient harm. Brand drug manufacturers could be in the position of neither providing rebates off of list prices nor providing upfront discounts from list prices.

This danger is real. FDA Commissioner Gottlieb, before his appointment, testified to Congress that antitrust precedent led manufacturers to insist on use of rebates, that manufacturers have refused to provide upfront discounts based on the perceived legal risks, and that, before restricting rebates, legislative changes are needed to ensure that manufacturers provide upfront discounts. The proposed reform needs to account for the high risk of manufacturer inaction and higher prices.

### **II. The Policy Blueprint Proposes Restrictions on Drug Rebates**

The Blueprint includes proposed changes to the rebate system that would impact price negotiations between brand drug manufacturers and managed care organizations.<sup>1</sup> HHS has requested public comments by July 16, 2018. The Blueprint identifies four “key strategies” for reform, with one strategy focusing on a reduction in list prices for pharmaceuticals.<sup>2</sup>

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<sup>1</sup> See Department of Health and Human Services, “American Patients First” policy proposal (May 2018), <https://www.hhs.gov/sites/default/files/AmericanPatientsFirst.pdf>.

<sup>2</sup> *Id.* at 9.

For each of the four “key strategies,” the Blueprint includes two phases of policy implementation: (1) actions that President Trump can direct HHS to “immediately implement” and (2) “further opportunities” that HHS is actively considering before implementing. The second phase includes opportunities to lower list pricing through changes to the rebate system.<sup>3</sup> These further opportunities include restricting the use of rebates by revisiting the safe harbor for drug manufacturers under the anti-kickback statute and additional reforms to the rebate system.<sup>4</sup>

As examples of further opportunities for rebate reform, the Blueprint also raises a series of questions for consideration.<sup>5</sup> These questions include:

- “Do PBM rebates and fees based on the percentage of the list price create an incentive to favor higher list prices (and the potential for higher rebates) rather than lower prices?”
- “Do higher rebates encourage benefits consultants who represent payers to focus on high rebates instead of low net cost?”
- “Do payers manage formularies favoring benefit designs that yield higher rebates rather than lower net drug costs?”
- “Should PBMs be forbidden from receiving any payment or remuneration from manufacturers, and should PBM contracts be forbidden from including rebates or fees calculated as a percentage of list prices?”
- “What effect would imposing this fiduciary duty on PBMs on behalf of the ultimate payer (i.e., consumers) have on PBMs' ability to negotiate drug prices?”
- “What should CMS consider doing to restrict or reduce the use of rebates?”
- “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?”

The Blueprint raised these questions without attempting to answer them. The questions suggest that HHS may take action to restrict rebates with the hope that brand drug manufacturers will

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<sup>3</sup> *Id.* at 11.

<sup>4</sup> *Id.*

<sup>5</sup> *Id.* at 33-34.

lower list price or provide upfront discounts.

### **III. In the 1990s, Brand Drug Manufacturers Settled Antitrust Litigation Challenging Their Use of Upfront Discounts**

Responses to these questions and later policy reforms must account for important antitrust conditions underlying the brand drug manufacturer behavior that led to this system. The rebate system that prevails today was largely shaped by a series of private antitrust lawsuits brought in the 1990s by pharmacies against brand drug manufacturers.<sup>6</sup> These cases were consolidated in a federal antitrust class action, *In re Brand Name Prescription Drugs Antitrust Litigation*.<sup>7</sup>

In *Brand Name Prescription Drugs Antitrust Litigation*, pharmacies alleged that brand drug manufacturers provided more favorable prices to managed care payers through use of upfront discounts and that this amounted to illegal price discrimination under the Robinson-Patman Act.<sup>8</sup> The pharmacies alleged that managed care payers, but not pharmacies, received upfront discounts from brand drug manufacturers.<sup>9</sup> According to the pharmacies, the manufacturers refused to make the upfront discounts available to them.<sup>10</sup> The pharmacy plaintiffs cited an internal memorandum from one manufacturer discussing the use of these “upfront deposit/credits” with managed care as evidence of anticompetitive conduct.<sup>11</sup> Manufacturers allegedly agreed to these discounts only with “favored classes of customers,” who were managed care payers.<sup>12</sup> Plaintiff pharmacies asserted that manufacturers refused to even discuss the issue of discounts with retail pharmacies.<sup>13</sup>

To end the class action litigation, the drug manufacturers settled the antitrust claims for over \$350 million.<sup>14</sup> The federal court approved a settlement that included restrictions on future

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<sup>6</sup> See S. Gottlieb, *How Congress Can Make Drug Pricing More Rational*, FORBES (Sept. 12, 2016), <https://www.forbes.com/sites/scottgottlieb/2016/09/12/how-congress-can-make-drug-pricing-more-rational/2/#26155e936532>.

<sup>7</sup> *In Re Brand Name Prescription Drugs Antitrust Litigation*, 94 C 897, MDL 997 (N. D. Ill. 1994).

<sup>8</sup> *In Re Brand Name Prescription Drugs Antitrust Litigation*, 94 C 897, MDL 997, 1996 WL 167350, at \*2 (N.D. Ill. Apr. 4, 1996).

<sup>9</sup> *In Re Brand Name Prescription Drugs Antitrust Litigation*, 94 C 897, MDL 997, 177 F.R.D. 414, 417 (N.D. Ill. 1997).

<sup>10</sup> *In Re Brand Name Prescription Drugs Antitrust Litigation*, 94 C 897, MDL 997, 1996 WL 167350, at \*2 (N.D. Ill. Apr. 4, 1996).

<sup>11</sup> *Id.* at \*8.

<sup>12</sup> *In Re Brand Name Prescription Drugs Antitrust Litigation*, 123 F.3d 599, 603 (7th Cir. 1997).

<sup>13</sup> *In Re Brand Name Prescription Drugs Antitrust Litigation*, 94 C 897, MDL 997, 1996 WL 167350, at \*1 (N.D. Ill. Apr. 4, 1996).

<sup>14</sup> See *Judge Agrees to Settlement in Drug Case*, THE NEW YORK TIMES (June 22, 1996), <https://www.nytimes.com/1996/06/22/business/judge-agrees-to-settlement-in-drug-case.html>.

pricing.<sup>15</sup> In the settlement agreement, the drug manufacturers agreed that, with limited exceptions, they would offer retail pharmacies the same discounts offered to managed care payers.<sup>16</sup>

While the litigation challenged the manufacturers' upfront discount practices, the use of rebates was not condemned by the court. Rather, the court viewed rebates as inherently pro-competitive. In one of the rulings in this litigation, Judge Posner of the Seventh Circuit Court of Appeals found that "the chargeback system [based on rebates paid from manufacturers to drug wholesalers] . . . is supported by commercial reasons independent of any desire to . . . facilitate collusive pricing" and that the rebate system has "innocent commercial virtues."<sup>17</sup>

#### **IV. Drug Manufacturers Responded to the Antitrust Precedent by Changing Their Pricing Practices to Offer Rebates**

*Brand Name Prescription Drugs Antitrust Litigation* led drug manufacturers to change their approach to pricing. Manufacturers moved away from upfront, volume-based discounts. In their place, manufacturers shifted to the use of back-end rebates. To incent manufacturers to lower prices, 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 to 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 through a convoluted system on the back end of the transaction, rather than an up-front discount on the drugs?"<sup>18</sup> 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."<sup>19</sup>

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<sup>15</sup> *In Re Brand Name Prescription Drugs Antitrust Litigation*, 94 C 897, MDL 997, 1996 WL 351180 (N.D. Ill. June 24, 1996).

<sup>16</sup> *Id.*

<sup>17</sup> *In re Brand Name Prescription Drugs Antitrust Litigation*, 288 F.3d 1028, 1034-35 (7th Cir. 2002) (Posner).

<sup>18</sup> 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, <https://www.help.senate.gov/download/testimony/gottlieb-testimony>.

<sup>19</sup> S. Gottlieb, *How Congress Can Make Drug Pricing More Rational*, FORBES (Sept. 12, 2016), <https://www.forbes.com/sites/scottgottlieb/2016/09/12/how-congress-can-make-drug-pricing-more-rational/2/#26155e936532/>, ("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.").

Based on their interpretation of the antitrust precedent, manufacturers concluded that they could make the rebate model available to all—both PBMs and smaller pharmacy purchasers—knowing that the smaller purchasers may be unable to meet the manufacturers’ requirements to qualify for the rebates. Scott Gottlieb testified: “These rebates are based on complex formulas tied to some measure of units of a drug that are sold. The idea was that these rebates could be offered to everyone, including pharmacies. But the pharmacies would never be able to satisfy the burden of evidence to qualify for the rebates.”<sup>20</sup> As Scott Gottlieb testified, the manufacturers believed that “[o]nly health plans could make the required representations related to how many units of a particular drug it sold.”<sup>21</sup>

The same findings come from other studies of industry pricing. For example, *The Source on Healthcare Pricing and Competition*, a non-profit initiative by UC Hastings, published an analysis entitled: “A Drug Rebate’s Tale: How a Class Action Lawsuit in the 90s Shaped Drug Pricing.”<sup>22</sup> This analysis explained that after the settlement, manufacturers wanted to make any price cuts contingent on the payers or pharmacies demonstrating that specific drug sales exceeded a “market share” threshold for a therapeutic class or other category.<sup>23</sup> On the surface, the manufacturer’s rebate model would be offered to all and thus manufacturers believed this reduced antitrust risks. Under this approach, the price cuts or rebates would be “calculated retrospectively” and manufacturers “structured the agreements in a way that pharmacies were unable to provide the evidence to prove qualification for the rebates.”<sup>24</sup>

## **V. Legislative Change Is Needed to Prevent Large Drug Price Increases if Manufacturers Cannot Offer Rebates**

The proposed policy changes would leave untouched the antitrust precedent and laws invoked by manufacturers to end upfront discounting. Moving forward on this basis is dangerous to consumers. Manufacturers would cease cutting prices through rebates. And they would refuse to provide upfront discounts because of antitrust precedent. Drug prices will be

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<sup>20</sup> 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, <https://www.help.senate.gov/download/testimony/gottlieb-testimony>; see also S. Gottlieb, *How Congress Can Make Drug Pricing More Rational*, FORBES (Sept. 12, 2016), <https://www.forbes.com/sites/scottgottlieb/2016/09/12/how-congress-can-make-drug-pricing-more-rational/2/#26155e936532> (“But the drug makers knew that the retailers couldn’t possibly fulfill the burden of proof needed to qualify for the rebate. . . . For obvious reasons, the drug makers don’t want to write contracts with the insurers that the retailers could also demand.”).

<sup>21</sup> 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, <https://www.help.senate.gov/download/testimony/gottlieb-testimony>.

<sup>22</sup> K. Gudiksen, Senior Research Fellow, THE SOURCE ON HEALTHCARE PRICING AND COMPETITION (Feb. 23, 2018), <http://sourceonhealthcare.org/a-drug-rebates-tale-how-a-class-action-lawsuit-in-the-1990s-shaped-drug-pricing/>.

<sup>23</sup> *Id.*

<sup>24</sup> *Id.*

significantly higher as list prices remain the same, but no rebates are passed along to the health plan sponsors to reduce premiums or prices at the point of sale.

Congressional action would be needed to solve this problem. Scott Gottlieb and others have recognized the importance of legislative change to ensure manufacturers will provide upfront discounts.<sup>25</sup> There is too much risk to consumers in the absence of legal change.

It will be important to ensure that payers for government and commercial plans retain the tools needed to incent manufacturers to lower price. In particular, the use of formularies that reward volume or share in exchange for price cuts must remain available as a check on manufacturer pricing.

The necessary legal change could be accomplished by an amendment to the Robinson-Patman Act, the federal law governing price discrimination. At the front end, manufacturers could price differently based on differences in volume or share commitments. That pricing approach, when done at the front-end, can be exempt from the Robinson-Patman Act. This change is needed to ensure that any change barring rebates does not leave consumers vulnerable.

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<sup>25</sup> 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, <https://www.help.senate.gov/download/testimony/gottlieb-testimony> (“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.”); S. Gottlieb, *How Congress Can Make Drug Pricing More Rational*, FORBES (Sept. 12, 2016), <https://www.forbes.com/sites/scottgottlieb/2016/09/12/how-congress-can-make-drug-pricing-more-rational/2/#26155e936532>, (“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.”); K. Gudiksen, Senior Research Fellow, THE SOURCE ON HEALTHCARE PRICING AND COMPETITION (Feb. 23, 2018), <http://sourceonhealthcare.org/a-drug-rebates-tale-how-a-class-action-lawsuit-in-the-1990s-shaped-drug-pricing/> (“In addition, allowing pharmaceutical manufacturers to offer discounts rather than rebates to health plans and PBMs that create formularies could meaningfully increase the competition between drugs and alternative treatment options.”).