

From the SDNY Whistleblower Complaint filed August 3, 2018

PART D ORIGINS OF THE “SERVICE FEE” SCHEME

721. Before Medicare Part D, the dominant PBMs made virtually all their profits from the portion of “rebates” they “retained” from their negotiations with manufacturers on behalf of their private insurance clients.

722. In the private sector, aggressive PBM “rebate” negotiations with manufacturers were essential for controlling drug costs and preventing severe price increases. As compensation, the PBM kept (i.e., “retained”) a significant, but often secretive, portion of these rebates.

723. Concerns regarding potential manufacturer/PBM collusion regarding “rebates” led to several major PBM lawsuits and settlements just as Medicare Part D was coming to fruition. On September 7, 2005, a Settlement Agreement was entered into between the United States, the PBM Advanced PCS and three Relators (Brown, Waite and Schulmann). In the settlement, AdvancePCS paid the sum of \$137.5 million to resolve allegations brought forth by the US government.

724. On March 24, 2004, Advance PCS became a wholly-owned subsidiary of Caremark Rx, Inc. Subsequently, on March 22, 2007, Caremark Rx merged with CVS to form CVS Caremark (now renamed CVS Health), one of the largest PBM Defendants.

725. The Justice Department made a similar Settlement Agreement in 2006 with another PBM, Medco Health Solutions. Medco merged with PBM Defendant Express Scripts in April 2012.

726. Despite these and other legal matters, as well as widespread concerns about their business practices, last decade PBMs were charged with the central role of “negotiating” in good faith with drug manufacturers on behalf of beneficiaries and taxpayers in the then new Medicare Part D program.

727. Cognizant of the central role of “manufacturer rebates” in the private insurance sector, Congress legislated assuming similar dynamics in the Part D program. Congress expected PBMs to aggressively negotiate with manufacturers for rebates/discounts on behalf of Part D beneficiaries and to be compensated by “retaining” a portion of the savings.

728. Congress required full disclosure of “rebates”, including the portion kept by the PBMs, and their deduction from Part D “negotiated” prices in order lower drug costs for beneficiaries and the program. As such, compensation of PBMs by manufacturers via “rebates” in Part D would lead to lower drug prices and lower future industry profits, particularly regarding the competitively-challenged Defendant products.

729. Part D also requires full disclosure of brand drug pharmacy “price spreads”, thereby limiting another prior key source of revenues/profits for the dominant PBMs. The abuse of brand drug “price spreads” was the central focus of the wide-ranging Average Wholesale Price (AWP) litigation, which resulted in more than \$3 billion in pharmaceutical industry Qui Tam and RICO settlements.

730. In sharp contrast to rebates, legitimate BFSFs from manufacturer to PBMs (and other service providers) are the only major financial item excluded from government drug price calculations, including from Part D “negotiated” prices.

731. PBM compensation via BFSFs would lead to lower rebates and higher drug prices for both collusive partners. In fact, BFSFs became the only pathway for significant non-transparent payments between manufacturers and PBMs/specialty pharmacies in the Part D program.

732. By linking the “service fee” model to vast drug price increases, both manufacturers and PBMs could garner staggering profits. The vast majority of the rising drug costs would be borne primarily by taxpayers in Part D (via the program’s various subsidies) and by largely

unaware clients in the private sector.

733. Obviously, this new business model is counter to the intent of the Part D program, which sought legitimate negotiation between PBMs and manufacturers and affordable drugs costs for beneficiaries and taxpayers.

734. It is not surprising that the Defendants quickly pursued their own self-interest by secretly switching from the “rebates” to the “service fee” business model with the arrival of Medicare Part D. What is surprising is the astounding magnitude to which they have advanced the scheme.

735. Our investigation indicates that both the design of Part D and industry competitive threats contributed to the Defendants’ aggressive pursuit of this fraudulent pricing scheme.

736. Most importantly, massive US brand drug patent expirations over the past decade decimated the prior largely secretive PBM “rebate”-based compensation model.

737. Starting around the time of Part D’s arrival, virtually all the top brand drugs in the former top-spending primary care therapeutic categories lost patent protection, including the cholesterol lowering, anti-hypertensive, antidepressants, anti-ulcer and antihistamines drug segments. As a result, generics now account for 90+% of US prescription volume, compared to about 50% a decade ago.

738. These patent expirations left the biopharmaceutical industry, but especially the Manufacturer Defendants, increasingly dependent upon a small number of remaining brand drugs, many of which also faced severe competition from new entrants.

739. The PBM financial opportunity from manufacturer brand drug rebates, their prior primary source of profits, also plummeted along with the widespread patent expirations.

740. Unfortunately, to the extreme detriment of the American public, rather than

accepting the sharply deteriorating competitive market reality, the senior executives at these Defendant companies intentionally chose a fraudulent path for their corporate and personal financial gain.