From the SDNY Whistleblower Complaint filed August 3, 2018

PART D LEGISLATIVE HISTORY AND KEY GOVERNMENT DATA

751. When the Medicare Part D program began, both legislators and CMS expected private competition to generate significant cost savings for seniors and to hold down drugs prices.

752. In October 2003, as Congress was debating the Medicare Part D legislation, President George W. Bush claimed: "The best way to provide seniors with modern medicine, including prescription drugs coverage...is to give them better choices under Medicare. If seniors have choices, health plans will compete for their business by offering better coverage at more affordable prices." The White House, President Calls on Congress to Complete Work on Medicare Bill (Oct. 29, 2003).

753. In November 2003, Secretary of Health and Human Services, Tommy Thompson, stated: "Health insurance companies are going to get into this market...The pharmaceutical benefit managers (PBMs) who will be taking over purchasing of the drugs are going to be able to purchase in bulk with the pharmaceutical companies and hold down prices." (Emphasis added) The Big Story with John Gibson, Fox News Network (Nov. 26, 2003).

754. Key government officials actually suggested Medicare Part D drug cost savings would be even greater than in other federal drug programs, such as Medicaid.

755. While awaiting implementation of the program, in September 2004, Medicare Administrator Mark McClellan claimed that the private insurers would be able to obtain "the best" prices for seniors. He stated: "Our approach is expected to provide the best discounts on drugs, discounts as good or better than could be achieved through direct government negotiation." (Emphasis added) Testimony of Dr. Mark McClellan, Senate Finance Committee, Hearing on The Medicare Prescription Drug Benefit, 109th Cong. (Sept. 14, 2005).

756. Legislative proponents and CMS clearly expected significant "negotiated" rebates/price concessions from drug manufacturers to be the primary method to limit elderly drug costs, to prevent severe brand drug price inflation and to compensate PBMs and other service vendors for their efforts in the Medicare Part D program.

757. Our investigation has found no public evidence of legislative debate regarding the role of “Bona Fide Service Fees” (“BFSFs”) in Medicare Part D, with the issue remaining largely out of the public eye even now, more than a decade since the program's inception.

758. Counter to these expectations, considerable brand drug inflation in Medicare Part D commenced as soon as the program was implemented in January 2006.

759. According to CMS's own data reported in comments to a January 2010 General Accounting Office (GAO) report (GAO-10-242): "An internal CMS analysis revealed a more than 30 percent increase in the price indices of brand name drugs (both specialty and non-specialty tier) between January 2006 and October 2009."

760. In addition, counter to the CMS expectations, the percentage rate of rebates in Medicare Part D have been modest compared to other federal drug programs. Since inception, manufacturer rebates have averaged about 10%, with a modest increase to the 15% range in recent years. Medicare Trustee Annual Reports.

761. Compared to Part D, manufacturer rebates in the Medicaid program have been far larger, averaging 34% of program spending for the years 2006 through 2009. OIE-03-10-00320, Higher Rebates for Brand-Name Drugs Result in Lower Costs for Medicaid Compared to Medicaid Part D, August 2011.

762. The far larger rebate proportion in Medicaid is because its statutes, in sharp contrast to Medicare Part D, require that manufacturers provide additional rebates to CMS for any revenues

generated by brand drug price increases on marketed products greater than general inflation (CPI-U, Consumer Price Index-Urban).

763. With ongoing severe Part D price inflation, OIG's most recent comparison of Medicaid and Medicare Part D indicated further divergence in rebate trends. For the year, 2012, rebates for the top-spending 200 brand drugs in Medicare D were 15% of the program's spending versus 47% for Medicaid. OIE-03-10-00650, Medicaid Rebates for Brand-Name Drugs Exceeded Part D Rebates by a Substantial Margin. Higher Rebates for Brand-Name Drugs Result in Lower Costs for Medicaid Compared to Medicaid Part D, April 2015.

764. In March 2011, the Office of Inspector General (OIG) of the Department of Health and Human Services released a report entitled "Concerns with Rebates in the Medicare Part D Program". OIG HHS Report, OEI-02-08-00050, March 2011. The OIG analysis was based on all Part D sponsor rebate reports and plan bid data for 2008, as well as an in depth review of six selected sponsors.

765. The OIG report disclosed that Medicare Part D sponsors reported receiving $6.5 billion in drug manufacturer rebates in 2008, corresponding to approximately 10% of total gross Part D drugs costs of $63 billion for the year.

766. However, central to these fraud allegations and contrary to legislative expectations, PBMs "retained" less than 1% or only $24 million of the $6.5 billion (Emphasis added) in total manufacturer rebates reported to CMS in plan sponsor "Direct and Indirect Remuneration" ("DIR") reports for 2008.

767. In addition, 61% of plan sponsors reported that PBMs retained no Part D rebates in 2008.

768. As such, counter to legislative and public expectations, PBMs received minimal

rebate compensation from drug manufacturers in 2008. Of note, this OIG report is the only federal document we have been able to locate which discusses manufacturer rebates "retained" by PBMs in the Part D program.

769. Since BFSFs were, by law, the only significant payments excluded from Part D sponsor DIR reports in 2008, virtually all PBM compensation for that year, beyond the minimal reported “retained” rebates, came in the form of BFSFs from manufacturers.

770. Additional direct CMS data confirms both extreme price increases and very low level of rebates for many high-cost “specialty” drugs in Part D.

771. In January 2010, the General Accounting Office (GAO) released a report (GAO-10-242), entitled: Medicare Part D – Spending, Beneficiary Cost Sharing, and Cost Containment Efforts for High-Cost Drugs Eligible for Specialty Tier”. The study analyzed “specialty” drug pricing and manufacturer price concession trends in the first three years of Part D, 2006 through 2008.

772. In the analysis, the GAO obtained “specialty” drug pricing and price concession data for 20 key specialty drugs from 7 large plan sponsors, which represented 51% of all Medicare Advantage Part D enrollment and 67% of standalone Part D enrollment in 2008.

773. In the report, the GAO identified ten chronic conditions commonly treated with “specialty” drugs; then selected two therapies for evaluation from each therapeutic category.

774. For all reviewed “specialty” drugs, the GAO found the level of discounts/rebates was below the 9-11% average in the Medicare Part D program throughout the 2006-2008 period. In addition, the Medicare Part D costs per patient had risen considerably for major “specialty” drugs, due to severe price inflation.

775. In the multiple sclerosis category, negotiated discounts for Biogen's Avonex were

only 1.1-2.6% of list price, despite a 35% price increase over the two years. Discounts for Teva's MS therapy were modestly higher, at 6.2-8.0% of list price during the period, with a 26% increase in cost of therapy over the two years.

776. In the anti-TNF category, negotiated discounts for AbbVie's Humira were in the 6.1-8.2% of list price range, with 9% price inflation over the two years. For Amgen's Enbrel, negotiated discounts were lower, at 2.0-3.7% of list price, with 7% price inflation between 2006 and 2008.

777. In the cancer space, no negotiated discounts were provided in any year for Novartis' Gleevec and Roche's Tarceva (an oral drug for lung cancer), despite 24% and 13% price escalation, respectively, between 2006 and 2008.

778. The magnitude of price increases for the above noted “specialty” drugs and many other brand products has greatly accelerated since this dated GAO study.