From the SDNY Whistleblower Complaint, filed on August 3, 2018

EVIDENCE OF SEVERE PART D CATASTROPHIC "COST-SHARING" FRAUD

395. The escalating "service fee" scheme for extreme-priced "specialty" drugs has also fueled severe financial fraud regarding essential Part D plan sponsor "catastrophic" cost-sharing requirements.

396. The evidence of "catastrophic" abuse has particularly escalated in the recent years, with the annual patient cost of "specialty" drugs now routinely in the $70-200,000 or more price range.

397. In Part D, taxpayers (via the Part D "Reinsurance Subsidies") cover 80% of all drug costs for any beneficiary crossing a modest annual "catastrophic threshold", which was $3,600 in 2006 and rose to $5,000 in 2018.

398. For extreme-priced "specialty" drugs, typically with an annual treatment cost now in the $70-200,000 range ($5,000-16,700 or more per month), most treated Part D patients now cross the "catastrophic threshold" in the first 1-2 months of each calendar year.

399. In order to incentivize aggressive price negotiation with manufacturers, Part D requires plan sponsors to cover an unlimited 15% of all "catastrophic" spending for beneficiaries.

400. This "cost sharing" requirement is the central Part D mechanism to incentivize cost control and legitimate negotiation with drug manufacturers regarding extreme-priced "specialty" drugs in the program.

401. However, as noted previously, since the PBM Defendants serve all three key functions (plan sponsor, PBM and specialty pharmacy) for the majority of Part D plans and beneficiaries, this "independent" plan sponsor function has been compromised.

402. The failure of this essential cost-control mechanism is indicated by the vast increase

in Part D "catastrophic" spending in recent years.

403. Massive unanticipated "catastrophic" over-spending has been the primary driver of accelerating Part D spending in recent years. In 2016, Part D "catastrophic" spending was $34.8 billion, up more than 3-fold just since 2010 and from only $6 million in 2006.

404. "Catastrophic" spending accounted for less than 15% of Part D spending in 2006, rising to 38% of program spending in 2016. According the 2017 Medicare Trustees Report, "catastrophic" spending is forecasted to be $42.1 in 2018 and more than $80 billion by 2026, remaining the primary driver of Part D spending growth.

405. The "catastrophic" overspending in recent years has been fueled by the massive inflation of older "specialty" drugs, as well as the broad Part D use of new hepatitis C therapies and extreme-priced cancer drugs.

406. In a properly-functioning marketplace, this excess spending should have placed an extreme financial burden on Part D plan sponsors, including the dominant PBM Defendants.

407. A MedPAC report from June 2015 indicated that plan sponsors had under-forecasted Part D "catastrophic" spending by more than $6 billion in 2013 (or by more 50%) of the actual "catastrophic" spending of $19 billion for the year. MedPAC Report to Congress: Medicare and the Health Care Delivery System, June 2015, Chapter 6, "Sharing Risk in Medicare Part D".

408. Consistent with their dominant plan sponsor role in the Part D program, in the MedPAC report 70% of the unforeseen "catastrophic" spending was attributed to the four largest PBM Defendants, Express Scripts, CVS Health, UnitedHealth Group and Humana.

409. At the 15% cost-sharing rate, the $6 billion in excess Part D "catastrophic" spending in 2013 corresponds to unforeseen plan sponsor additional "cost-sharing" exposures of

more than $900 million just for that single year for all plan sponsors and about $630 million for the four largest PBM Defendants.

410. Furthermore, the bid, premium and actual "catastrophic" spending data suggest a further marked acceleration in unforeseen plan sponsor "cost-sharing" for 2014 and 2015.

411. Aggregate plan sponsors forecasted a 40% increase in Part D "catastrophic" spending between 2013 and 2015. The actual 2015 "catastrophic" spending came in at $33.2 billion, 73% higher than 2013.

412. We estimate Part D plan sponsors (i.e., primarily the PBM Defendants) underestimated combined 2014 and 2015 "catastrophic" spending by another $10 to $20 billion.

413. This additional program spending led to an estimated $1.5 to $3.0 billion in unforeseen "cost sharing" expenses for aggregate Part D plan sponsors for 2014 and 2015 combined, with the four largest PBM Defendants responsible for about $1.1 to $2.1 billion.

414. Despite this large unforeseen "cost-sharing" burden, all the PBM Defendants have reported robust financial results for 2013-2015 and none has indicated significant financial challenges in Part D.

415. This fact is inconsistent with both the huge financial burden faced by the PBM Defendants from the "catastrophic" over-spending and the typically low operating profit margins (5-6% range) for Part D plan sponsors in their annual bids submitted to CMS.

416. In reality, the massive "catastrophic" cost over-runs should have reeked financial havoc among PBM Defendants in Part D, but it never materialized.

417. To put the magnitude of this unforeseen plan sponsor cost-sharing burden in perspective, the Part D plan bids for all sponsors across the nation in 2007 included "expected profits" of only $1.07 billion. GAO Report OEI-02-08-00460, Medicare Part D Reconciliation

Payments for 2006 and 2007, September 2009.

418. Based upon the 2015 plan bids (average $130/beneficiary) and annual enrollment (39.2 million people), we estimate aggregate Part D profits in the $3.0-3.5 billion range for aggregate US Part D plan sponsors for 2015.

419. There is no mathematical possibility that the dominant PBM Defendants could handle these massive unforeseen 2013-2015 "catastrophic" cost-sharing requirements (approximately $2.4 to $3.9 billion), without severe disruption to their financial performance and the overall Medicare Part D program.

420. This amount of unforeseen "catastrophic" cost-sharing would have negated virtually all Part D profits for the three year period.

421. The only way the PBM Defendants could avoid the tremendous dislocation from this unforeseen "cost sharing" exposure is through another secretive fraudulent financial arrangement with drug manufacturers.

422. We concluded that, in many instances, manufacturers are fraudulently excusing the PBM Defendants from their 15% "catastrophic" cost-sharing exposure (in their role as plan sponsors), in order to advance the now pervasive "service fee" pricing scheme.

423. We will Novartis' Gleevec to illustrate the scale of potential plan sponsor "cost-sharing" fraud. See **Exhibit 13**.

424. The annual AWP cost/patient of Gleevec increased from about $38,572 in 2006 to the $147,788 in 2015, prior to its early 2016 US patent expiration. In 2015, Gleevec was the second top-spending cancer drug in Part D (after only Celgene's Revlimid).

425. In Part D, in 2006, the plan sponsor would be responsible for 15% of all Gleevec costs above the $3,600 threshold, or about $5,246 in annual costs, payable to the manufacturer,

Defendant Novartis.

426. After the massive price increases, the PBM Defendants (in their role as plan sponsor) would be responsible in 2015 for nearly $21,463 in "cost-sharing" for each Part D Gleevec-treated patient above the modest $4,700 threshold that year.

427. With these dynamics, it would appear mathematically impossible for the dominant PBM Defendants to pay the escalating plan sponsor Gleevec "cost-sharing" burden driven by the massive price increases.

428. The 15% plan sponsor "cost-sharing" burden would be nearly twice as much as the "service fees" received from a standard "8% of revenue" "specialty" drug contract, leading to considerable losses for the PBM Defendant.

429. With apparently minimal, if any, "rebates" for Gleevec and other oral cancer "specialty" drugs, Novartis "service fees" for Gleevec are the sole source of PBM Defendant profits related to the product.

430. Beyond Gleevec and the other Defendant CML drugs, we suspect widespread abuse of the Part D plan sponsor "catastrophic" cost-sharing requirements for a wide array of extreme-priced oral "specialty" cancer drugs.

431. Just a few of the numerous other fast-inflating oral cancer "specialty" drug candidates for severe "service fee" and "catastrophic" abuse include: Celgene's Revlimid (myeloma, Part D's top-spending cancer drug, AWP $225,000 patient/year), Johnson & Johnson's Imbruvica (leukemia, AWP $178,000 patient/year), Bayer's Nexavar (renal cell/liver cancer, AWP $136,000 patient/year), Roche's Tarceva (lung cancer, AWP $123,000 patient/year) and Tesaro's Zejula/Clovis' Rubraca/Astra Zeneca's Lynparza (PARP inhibitors for ovarian cancer, AWP $215-300,000 patient/year).

Exhibit 13
Medicare Part D: "Catastrophic" Cost-Sharing Fraud
Novartis's Gleevec

	2006	2015	Change 2006-2015
AWP Cost/Patient/Year ($)	**$38,572**	**$147,788**	**$109,216**
Annual Part D Catastrophic Threshold ($)	$3,600	$4,700	
Drug Costs Above Catastrophic Threshold ($)	**$34,972**	**$143,088**	**$108,116**
PBM/Plan Sponsor Catastrophic Cost Sharing (%)	15%	15%	-
PBM/Plan Sponsor Catastrophic "Cost Sharing" ($)	**$5,246**	**$21,463**	**$16,217**
PBM "Service Fees"/Gleevec Patient ($ @ 8%)	**$3,086**	**$11,823**	**$8,737**

Source: Redbook/Truven, CMS, PhRMA.

432. If the Manufacturer Defendants are commonly "forgiving" the PBM Defendants from their Part D "catastrophic" exposure, these amounts should be properly reported as discounts via Direct and Indirect Remuneration ("DIR") reports to CMS, serving to lower program "negotiated" drug prices.

433. However, with Part D reimbursement based on AWP "list" prices, we expect discovery to uncover wide-ranging "cost-sharing" reporting and financial fraud for Gleevec and other extreme-priced "specialty" oral cancer drugs.

434. These "forgiven" costs are another form of "kickbacks" and false claims required to advance the pervasive "service fee" pricing scheme.

435. Due to very limited public disclosure by either CMS or the Defendants, we have not attempted to estimate the magnitude of potential Part D plan sponsor "catastrophic" cost-sharing fraud.

436. However, in recent years, the Part D "cost-sharing" financial fraud likely exceeds that from direct "service fee" payments for many extreme-priced "specialty" drugs.

437. The underestimation of "catastrophic" spending in annual plan sponsor bids leads to artificially low Part D beneficiary premiums, which are beneficial to the both the PBM and Manufacturer Defendants.

438. Low Part D premiums are a key marketing tool for the PBM Defendants and have contributed to accelerating enrollment in recent years.

439. Both Defendant parties gain political capital from low Part D premiums. The Defendants, politicians and related parties frequently cite the low premium levels as indicative of Part D's success in controlling spending, while largely ignoring the exploding "catastrophic" Part D cost increases in recent years.

440. Of course, in a properly-functioning program, the Defendant strategy falls apart if the Part D plan sponsors were actually bearing their share of the vast "catastrophic" excess spending.

441. Key Part D regulatory shortfalls have contributed to fraudulent abuse of the Part D plan sponsor "cost-sharing" cost-control mechanism. If Part D plan sponsors were truly independent entities, "catastrophic" risk-sharing would force legitimate, aggressive price negotiations with manufacturers by the PBM Defendants.

442. Second and surprising to us, Medicare Part D does not require separate reporting and accounting (in PDE or any other CMS submissions) of the plan sponsor 15% "catastrophic"

cost-sharing requirement, despite it being the primary mechanism for controlling high-cost "specialty" drug spending.

443. These regulatory shortfalls regarding plan sponsor "catastrophic" cost-sharing shrouds this important issue in secrecy that requires full investigation in the public interest.

444. With "specialty" drugs now the primary driver of both the biopharmaceutical and PBM industries, the apparent failure of the plan sponsor "catastrophic" cost-sharing mechanism now threatens the long-term viability of the Part D program.