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July 12, 2019

Honorable Richard J. Leon
Senior Judge
U.S. District Court for the District of Columbia
333 Constitution Avenue, NW
Washington, D.C. 20001

Re: *United States v. CVS Health Corp.*, No. 1:18-cv-02340 (RJL)

Dear Judge Leon:

Amici Curiae Consumer Action and U.S. PIRG respectfully request leave to submit this letter for the limited purpose of responding to the June 19, 2019 letter submitted by Gary A. Loeber, Executive Vice President Pharmaceutical Contracting and Purchasing for CVS Health, Dkt. No. 118-1 ("Loeber Letter"). The principle assertion from the Loeber Letter – that "[t]he acquisition of Aetna will not have any impact on CVS Caremark's drug procurement" – is inconsistent with the purpose of CVS Caremark's Pharmacy Benefit Management ("PBM") business and is belied by CVS Health's own description of the nation's largest PBM business.[1]

The assertions in the Loeber Letter should be rejected for three reasons. First, any claims that the acquisition of Aetna's 19 million covered lives will not increase CVS Caremark's bargaining leverage are inconsistent with the market facts and CVS Health's own statements. Second, the increased bargaining leverage will harm consumers through higher prices. Third, CVS Caremark is not a mere conduit for its clients. We request that the Court discount the claims of the Loeber Letter and recognize that it does not diminish the clear evidence presented in the hearing that the Proposed Final Judgment ("PFJ") is not in the public interest.

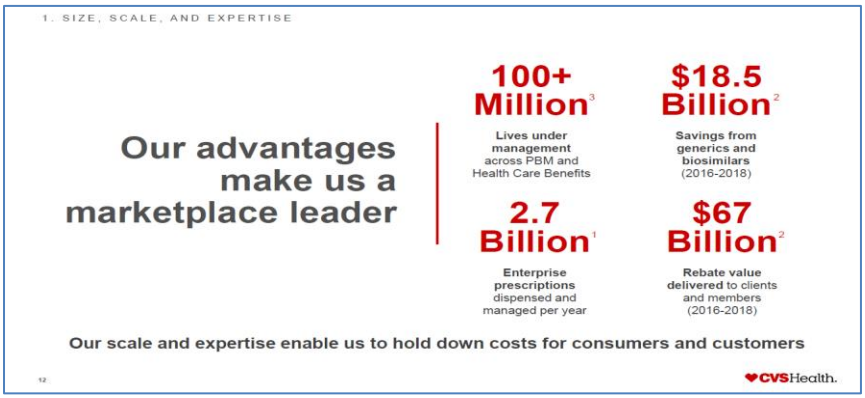
1. CVS Health's Increased Size and Scale Will Increase CVS Caremark's Bargaining Leverage

CVS Health all but evades the question it sets out to answer. The Court's request during the evidentiary hearing was clear: "whether the PBM part of the business has been strengthened in their negotiating ability as a result of this merger to date?" (Evidentiary Hr'g Tr. at 321). The

[1] Alia Paavola, Top PBMs by Market Share, May 30, 2019 (CVS largest PBM with 30% market share, followed by Express Scripts and OptumRx both with 23% market share, available at https://www.beckershospitalreview.com/pharmacy/top-pbms-by-market-share.html.

Loeber Letter pays lip service to the scope of the Court's request in the first paragraph, but then purports to answer only that "[CVS Caremark's] rebate negotiations and contracts are not tied to CVS Caremark's total volume of lives or claims. As a result, [CVS has] not observed any marked change in our *rebate negotiations* since the acquisition closed." (Loeber Letter at 1, emphasis added). The Loeber Letter then acknowledges that only "7.5% of the billions of claims processed by CVS Caremark involved a rebatable drug," thus ostensibly refusing to provide any answer for a strengthening of negotiating ability with respect to 92.5% of the claims processed by CVS Caremark. Shortly thereafter, in a section dedicated to negotiations with manufacturers, the Loeber Letter discusses only "rebate rates with manufacturers" and opines that there has not been "any marked change in [] rebate negotiations since the acquisition closed." (Loeber Letter at 3).

The Loeber Letter's contention that CVS Health's acquisition of Aetna will not have any meaningful impact on CVS Caremark's negotiating ability is inconsistent with CVS Health's witness testimony at the hearing, CVS Health's and others' public descriptions of the PBM business. (Evidentiary Hr'g Tr. at 349) ("The PBM business is also a scale business."). The answer to the Court's direct question is a resounding, yes, the PBM business is a scale business, and the acquisition of the Aetna lives will increase CVS Health's bargaining leverage vis-à-vis manufacturers and pharmacies. Undoubtedly, CVS' entire business model is predicated upon leveraging its "Size, Scale, and Expertise" to extract value from others in the supply chain. CVS touted this reality as recently as its Investor Day Presentation last month:[2]



Lest there be any doubt of the role the acquisition of Aetna plays in CVS' plan, the company represented that "CVS + Aetna combination provides additional levers to drive value in specialty

[2] Jon Roberts, CVS Caremark Exec. Vice President and Chief Operating Officer, Establishing the Foundation for Transformation, CVS Inv. Day Presentation at 13 (June 4, 2019),https://s2.q4cdn.com/447711729/files/doc_events/2019/InvestorDay2019/2019-CVS-Investor-Day-Jon-Roberts-Presentation.pdf.

pharmacy under the medical benefit,"[3] though CVS describes this enhanced bargaining leverage as "proven purchasing economics."[4]

The fact that PBMs are a scale business and this leverage is crucial to their business model is a bedrock principle in the industry. In 2015, CVS' Senior Vice President and Assistant General Counsel explained to Congress that PBMs "are able to negotiate lower prices from pharmaceutical manufacturers because they have multiple clients, and therefore are able to negotiate larger volume discounts than individual plans."[5] CVS' website states that "[g]iven the combined membership of the plan sponsors they service, PBMs are able to effectively negotiate rebates from drug manufacturers…"[6] Just two months ago, the Chief Policy and External Affairs Officer for the Pharmaceutical Care Management Association, the PBM trade association, explained to Congress that "Pharmacy benefit management is a scale business. The PBMs competing in the marketplace have leverage with manufacturers because they are negotiating on behalf of significant total patient populations."[7] CVS Caremark competitor Express Scripts emphasized the same, explaining "…scale matters ... our scale helps level the playing field when a brand or generic competitor merges."[8]

Accordingly, CVS Health's increased size and scale will increase its bargaining leverage over brand and generic manufacturers as well as pharmacies.

2. CVS Health's Increased Bargaining Leverage Will Result in Higher Drug Prices

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[3] *Id*. at 19.
[4] Derica Rice, Exec. Vice President & President, CVS Caremark, *Evolving Strategy for a Changing Marketplace*, CVS Inv. Day Presentation at 5 (June 4, 2019), https://s2.q4cdn.com/447711729/files/doc_events/2019/InvestorDay2019/2019-CVS-Investor-Day-Derica-Rice-Presentation.pdf
[5] *Hearing on the State of Competition in the Pharmacy Benefit Manager and Pharmacy Marketplaces: Hearing Before the Subcomm. on Regulatory Reform, Commercial and Antitrust Law of the H. Comm. on the Judiciary* 114th Cong. (2017) (Testimony of Natalie Pons) https://www.govinfo.gov/content/pkg/CHRG-114hhrg97631/html/CHRG-114hhrg97631.htm.
[6] Pharmacy Benefit Managers Play an Important Role in Health Care, https://cvshealth.com/thought-leadership/cvs-caremark-facts/pbms-play-an-important-role.
[7] *Improving Drug Pricing Transparency and Lowering Prices for American Consumers: Hearing Before the Subcomm. on Health of the H. Comm. on Energy and Commerce*, 117th Cong. (2019) (Testimony of Kristin Bass, Chief Policy and External Affairs Officer at Pharmaceutical Care Management Association), https://docs.house.gov/meetings/IF/IF14/20190521/109551/HHRG-116-IF14-Wstate-BassK-20190521.pdf.
[8] *State of Competition in the Pharmacy Benefits Manager and Pharmacy Marketplaces: Hearing Before the Subcomm. on Regulatory Reform, Commercial and Antitrust Law of the H. Comm. on the Judiciary*, 114th Cong. (2015) (Testimony of Amy Bricker, Vice President Retail Contracting and Strategy, Express Scripts),https://www.govinfo.gov/content/pkg/CHRG-114hhrg97631/html/CHRG-114hhrg97631.htm.

The Loeber Letter claims that "[t]he acquisition of Aetna will not have any impact on CVS Caremark's drug procurement" because Aetna had already outsourced drug purchasing responsibilities to CVS. (Loeber Letter at 3). But this description fails to account for either the importance of size in the purchasing of prescription drugs or the critical role that an independent insurer plays in making sure drug purchase decisions are done with the best interest of beneficiaries in mind. Once the acquisition is consummated there is no longer an independent Aetna to police CVS Caremark's decisions. The combination of CVS Caremark and Aetna's size without any systemic check will result in nothing more than additional unconstrained bargaining power for CVS Caremark.

The Loebler Letter suggests that the supposed benefit from CVS Health's ability to obtain rebates will benefit consumers but the evidence is far more ambiguous. Rebates for formulary access may exclude new innovative drugs that may be lower priced and more effective from drug formularies. PBMs often make decisions on inclusion of a drug not based on clinical research, or evidence-based efficacy, but based on which manufacturer offers a higher rebate payment based on higher list prices.[9] This is why the Administration proposed eliminating rebates and encouraging discounts at the point of sale in Medicare Part D plans,[10] a reform supported by major consumer groups.[11] Unfortunately, the proposed rule was withdrawn and even if implemented would have done nothing for the commercial markets. [12]

Throughout the Loeber Letter, CVS Health never grapples with the central question of the merger's likely effects on the pharmaceutical supply chain. The acquisition of Aetna will enhance CVS Caremark's negotiating leverage in numerous ways, including over brand and generic manufacturers as well as pharmacies. It will give CVS Caremark the incentive and

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[9] Robin Feldman, *Why Prescription Drug Prices Have Skyrocketed?* Washington Post, November 26, 2018. As Professor Robin Feldman, one of the leading experts on healthcare policy, puts it, "the system contains odd and perverse incentives, with the result that higher–priced drugs can receive more favorable health-plan coverage, channeling patients toward more expensive drugs."

[10] Fraud and Abuse; Removal of Safe Harbor Protection for Rebates Involving Prescription Pharmaceuticals and Creation of New Safe Harbor Protection for Certain Point-of-Sale Reductions in Price on Prescription Pharmaceuticals and Certain Pharmacy Benefit Manager Service Fees, 84 Fed. Reg. 2,340 (Feb. 6, 2019) (to be codified at 42 C.F.R. pt. 1001).

[11] *See* Consumer Action, Consumer Federation of America, Consumer Reports, NETWORK Lobby for Catholic Social Justice, and U.S. PIRG, Comment on Proposed Rule on Fraud and Abuse: Removal of Safe Harbor Protection for Rebates Involving Prescription Pharmaceuticals and Creation of New Safe Harbor Protection for Certain Point-of-Sale Reductions in Price on Prescription Pharmaceuticals and Certain Pharmacy Benefit Manager Service Fees (Apr. 8, 2019), https://www.regulations.gov/document?D=HHSIG-2019-0001-19975 ("[W]e support HHS' proposed rule changes to eliminate rebates, thereby encouraging prices that more closely reflect actual costs, with competitive incentives to offer any discounts directly to patients at the pharmacy counter.").

[12] Caitlin Owens, *1 big thing … scoop: White House Kills The Rebate Rule*, July 11, 2019 available at https://www.axios.com/newsletters/axios-vitals-c38101f0-76f2-46d7-a15b-52cfc8b4ae36.html.

ability to engage in exclusionary conduct in several levels of the market. For instance, CVS will have more control over Aetna formulary decisions, which impacts both acquisition price and reimbursement rate, and ultimately therapeutic choices for customers. In generic markets, CVS Health exercises significant buying power through its Red Oak Sourcing joint venture with Cardinal Health.[13] CVS Caremark is not just a PBM, but it is the largest specialty pharmacy[14] and has virtually exclusive control over dispensing these drugs as well as the establishment of fee schedules for rival pharmacies. Past experience has shown that CVS uses vertical integration to limit consumer choice and prioritize profits over patient wellbeing.[15] CVS Health will likely use the additional lives from Aetna to engage in practices designed to generate more revenues through spread pricing, pricing abuse,[16] and unilateral mark-ups of prices for drugs that are static or even declining. In fact, the State of Ohio recently found that CVS Caremark "increased its rates for specialty drugs at the beginning of this year, even though the cost of many of them were dropping nationally…raising the markup to more than 1,700%, or more than $250 per pill" despite the availability of a $14.50 generic.[17]

3. CVS' Efforts to Hide Behind Formulary Construction are Unavailing

The Loeber Letter self-servingly suggests that CVS Caremark will not experience increased leverage because negotiations are based on "formulary configuration" for which

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[13] Adam Fein, Meet the Power Buyers Driving Generic Deflation, Drug Channels Institute (Feb 1, 2018) https://www.drugchannels.net/2018/02/meet-power-buyers-driving-generic-drug.html. "In December 2013, CVS Health and Cardinal Health announced a 50/50 generic drug buying joint venture that began operating in mid-2014 as Red Oak Sourcing, LLC. . . We estimate that Red Oak is now the largest buyer of generic drugs. CVS Health's 2015 acquisition shifted the generic purchasing volume of Target and Omnicare to Red Oak. In 2016, Cardinal Health began a multiyear agreement with OptumRx to supply generic and brand pharmaceuticals to OptumRx's mail and specialty pharmacies, including the Catamaran business. Before OptumRx's acquisition of Catamaran, OptumRx had purchased generics directly from manufacturers."

[14] Adam Fein, *The 2019 Economic Report on U.S. Pharmacies and Pharmacy Benefit Managers*, DRUG CHANNELS (March 5, 2019), https://www.drugchannels.net/2019/03/new-2019-economic-report-on-us.html. In the 2018 version of this report Drug Channels estimated that CVS Specialty was the largest specialty pharmacy with approximately 25% market share based on revenues. *See* Adam Fein, *The Top 15 Specialty Pharmacies of 2017: PBMs and Payers Still Dominate*, DRUG CHANNELS (March 13, 2018), https://www.drugchannels.net/2018/03/the-top-15-specialty-pharmacies-of-2017.html.

[15] Reed Abelson and Natasha Singer, Pressure Grows to Unwind CVS Merger, NY Times, April 14, 2011.

[16] *United States ex rel. John R. Borzilleri*, Case No. 1:15-cv-07881 (S.D.N.Y. filed 2018) (false claims case brought by relator alleging that PBMs, including CVS Caremark, conspired with brand drug manufacturers to conceal illegal payments as part of Bona Fide Service Fees (BFSFs) in excess of fair market value to enable massive price increases, gain formulary access, and prevent standard PBM cost-saving practices that would otherwise have reduced healthcare costs for PBM beneficiaries).

[17] Darrell Rowland, *Dispatch Analysis: State's Attempt to Curb Drug Middlemen Mostly Futile*, THE COLUMBUS DISPATCH (June 23, 2019), https://www.dispatch.com/news/20190623/dispatch-analysis-states-attempt-to-curb-drug-middlemen-mostly-futile.

"clients make decisions" and "the PBM implements those benefit decisions." (Loeber Letter at 1). This effort to describe itself as a simple agent of its customers is denied by market realities. Payors are often victimized by PBM tactics and the lack of transparency. As the Council of Economic Advisors observed, "[t]he size of manufacturer rebates and the percentage of the rebate passed on to health plans and patients are secret."[18] While PBMs claim they lower drug prices, they provide limited data regarding the acquisition price of prescription drugs to their own payors, even large ones. For example, in 2016, Anthem, the nation's second largest health insurer, sued Express Scripts for $15 billion, alleging that the PBM violated its contract by not passing along $3 billion a year in additional rebate pass-through amounts resulting in "massive damages to Anthem and an obscene profit windfall to Express Scripts."[19]

This also raises questions about CVS Health's claim in the Loeber Letter that 98% of the rebates are passed on to its clients.

The lack of transparency keeps customers in the dark.[20] For example, an Assistant Director of Benefits commented "[c]ontracts can be opaque and sometimes seeded with incentives that cause the vendor to act counter to the best interest of the health plan and consumers. Contracts have so many moving pieces and are so complex that you really need to have a very fine eye to understand all the nuanced ways that vendors are making money on these drugs."[21]

Experts echo these descriptions. Professor Robin Feldman has described PBM contracting practices as follows:[22]

> The contracts between PBMs and insurers are devilishly complex, using techniques that can camouflage the impact of particular provisions … Only the PBM sees the full drug company contract, along with all of the claims and utilization information for a particular plan. Secrecy and information asymmetries magnify the complexity problems, making it difficult for health insurers — particularly smaller plans — to see and learn from their mistakes … If true net pricing is hidden, the only players who see the net prices throughout the market are the large middle players (such as PBMs), who see the full picture across a range of drugs and a range of deals.

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[18] Reforming Biopharmaceutical Pricing at Home and Abroad, The Council of Economic Advisors, White Paper, February 2018.
[19] *Anthem, Inc. v. Express Scripts, Inc.*, No. 1:16-cv-02048-ER (S.D.N.Y. filed 2016).
[20] Adam Fein, *How Health Plans Profit—and Patients Lose—From Highly-Rebated Brand-Name Drugs*, DRUG CHANNELS (Feb. 20, 2019), https://www.drugchannels.net/2019/02/how-health-plans-profitand-patients.html.
[21] Joanne Sammer, *How HR Can Help Control Prescription Drug Costs*, SHRM (May 25, 2017), https://www.shrm.org/hr-today/news/hr-magazine/0617/pages/take-control-of-prescription-drug-costs.aspx.
[22] Robin Feldman, Drugs, Money, and Secret Handshakes 37 (1st ed. 2019).

As Professor Feldman points out, CVS Caremark has been accused by the federal government and the states of leveraging its size and strategic complexity to the detriment of clients, consumers, and taxpayers.[23] This conduct is illustrative of an industry that Professor Feldman described as "distorted by reimbursement schemes that reward the PBMs most significantly when drug prices and drug spending increases."[24]

The simple reality is that the interests of PBMs and payors are not fully aligned and there are significant conflicts of interest exploited by PBMs.

Conclusion

In summary, the Loeber Letter tries to disguise CVS Caremark's bargaining leverage and how this merger increases that leverage. In reality, CVS' PBM business model is predicated on size and scale, not formulary construction or relationship building, and CVS Health's acquisition of Aetna will unquestionably increase its bargaining leverage. CVS Health's protestations to the contrary are undercut by its own statements and documents presented to investors on the importance of its leverage in negotiations with drug manufacturers. In evaluating the CVS/Aetna merger, Amici urge the Court to evaluate the impact on the public interest from all angles and protect consumers by rejecting the PFJ.

Sincerely,

/s/ *David Balto*

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[23] *Id*. at 40 (discussing *United States ex rel. Sarah Benke v. CVS Caremark Corp*. (E. D. Pa. 2014) (No. 14-0824)). In that case, CVS Caremark was accused of "tricking the government into paying more for drugs, [so that CVS Caremark] could give lower prices to commercial plans."; *see also*, *id.* at 30 (discussing Press Release Dept. of Justice, CVS Caremark Corp. to Pay 336.7 Million to U.S., 23 states, and D.C. to Settle Medicaid Prescription Drug Fraud Allegations (Mar. 18, 2008)). In this instance, CVS Caremark agreed to pay $36.7 million to the U.S. government, 23 states, and the District of Columbia to settle claims that the company improperly switched patients from the tablet version of the ulcer and stomach-acid prescription drug, Ranitadine, to a more expensive capsule version, in order to increase Medicare reimbursements.

[24] *Id*. at 18.