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December 18, 2018

c/o  
Peter Mucchetti  
Chief, Healthcare and Consumer Products Section  
Antitrust Division  
Department of Justice  
450 Fifth Street NW, Suite 4100  
Washington, DC 20530

Re: *United States v. CVS Health Corp.*, No. 1:18-cv-02340, Comments  
from the Pharmacists Society of the State of New York

Dear Mr. Mucchetti:

We write on behalf of members of the Pharmacists Society of the State of New York (“Society”) who are pharmacists practicing across all settings, the majority being in community pharmacies. It is important to note that approximately half of the pharmacies in New York (over 2,300) are independently owned. In fact, about 10% of independent pharmacies in the country are here in New York. As we are committed to patient care, we often speak on behalf of our patients. Our membership has been heartened by the district court’s interest in the DOJ’s Proposed Final Judgment regarding the CVS Health – Aetna merger.

The Society submits these comments pursuant to the Antitrust Procedures and Penalties Act, 15 U.S.C. § 16 (“APPA” or the “Tunney Act”), to express our opposition to the settlement in this case. The Society does not believe that the settlement resolves the competitive problems raised by the CVS-Aetna merger because it does not address the vertical problems presented by the integration.

As Judge Leon stated in his December 3, 2018 Order to Show Cause, the district court, when evaluating a settlement, can examine if the complaint is so narrowly drafted as to “make a mockery of judicial power”. *United States v. Microsoft Corp.*, 56 F.3d 1448, 1462 (D.C. Cir. 1995); 15 U.S.C. § 16; *see also United States v. SBC Communications, Inc.*, 489 F. Supp. 2d 1, 14 (D.D.C. 2007) (where complaint “is drafted so narrowly as to make a mockery of judicial power,” the court has authority to reject consent decree “due to matters outside the scope of the underlying complaint.”).



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#### **PSSNY AFFILIATIONS:**

##### **National**

American Pharmacists Association  
American Society of Consultant Pharmacists  
National Alliance of State Pharmacy Associations  
National Community Pharmacists Association

##### **State Affiliates**

Bangladeshi-American Pharmacists Association  
Capital Area Pharmacists Society  
Hudson Valley Pharmaceutical Society  
Indo-American Pharmaceutical Society  
Italian-American Pharmacists Society  
Korean-American Pharmacists Association of NY  
Long Island Pharmacists Society  
Mohawk Valley Pharmacists Society  
New York City Pharmacists Society  
Northern New York Pharmacists Society  
Onondaga County Pharmacists Society  
Pakistani-American Pharmaceutical Association  
Pharmacists Association of the Southern Tier  
Pharmacists Association of Western New York  
Pharmacists Society of Orange County  
Pharmacy Society of Rochester  
Westchester & Rockland Society of Pharmacists

##### **NYS Colleges of Pharmacy**

Albany College of Pharmacy and Health Sciences  
Binghamton University School of Pharmacy and  
Pharmaceutical Sciences  
D’Youville College School of Pharmacy  
LIU, Arnold & Marie Schwartz College of  
Pharmacy and Health Sciences  
St. John’s University College of Pharmacy  
& Health Sciences  
Stony Brook University School of Pharmacy and  
Pharmaceutical Sciences  
Touro College of Pharmacy  
University at Buffalo School of Pharmacy  
and Pharmaceutical Sciences  
Wegmans School of Pharmacy, St. John  
Fisher College

Here, the DOJ ignored all of the vertical integration concerns presented by the CVS-Aetna merger. They are particularly troubling to community pharmacies in that the merger unites the nation's largest pharmacy chain, one of the three largest pharmacy benefit managers ("PBM") and a one of the Big 5 health insurers. To state the obvious, a large pharmacy chain is a direct competitor in the pharmacy marketplace. Perhaps less obvious is the impact that PBMs have on community pharmacies in their role as pharmacy network managers. Additionally, PBMs control drug formularies, thereby affecting which drugs are covered, at what co-pay amount and under which prior authorization regime. In short, PBMs control access to prescription drugs. Today just three PBMs account for 85% of the market.<sup>1</sup> CVS Health is the second largest in the United States managing approximately 34% of covered lives (approximately 90 million).<sup>2</sup> The problems raised by this acquisition and the increasing market power of CVS and its Caremark subsidiary cannot be understated. The Administrations Council of Economic Advisors recognized in a February 2018 report that three PBMs exercise undue market power against manufacturers and against the health plans and beneficiaries they are supposed to be representing, thus generating outsized profits for themselves.<sup>3</sup> This merger will increase the competitive problems by allowing CVS to acquire the third largest health insurer facilitating exclusionary conduct allowing them to increase prices and reduce choice. Based on experience, the Society holds the position that the new entity will increase healthcare costs, reduce patient choice and access, and cause the demise of local pharmacies.

The Society has raised serious concerns about the impact of the CVS-Aetna merger in testimony before the NYS Assembly Health and Insurance Committee Hearing in June and the NYS Department of Financial Services hearing in October of 2018. In addition, representatives of the Society met with DOJ officials in Washington in an effort to focus the Department on the serious concerns pharmacists have about the impact of the CVS Health-Aetna merger on patients, on pharmacies and on the healthcare delivery system as a whole. We are encouraged by the opportunity afforded by the Court's review of the DOJ Proposed Final Judgment and hope that the DOJ will reconsider its settlement agreement and move to challenge the merger.

The merger is a marriage of giants with market power. Aetna is the third largest health insurer in the United States with revenues of more than \$60 billion. In the PBM arena, CVS Health is the second largest entity controlling 34% of the market. In the first quarter of 2018 its reported revenue was \$32.2 billion. Merging the health insurer with the PBM-large pharmacy chain enterprise is the proverbial fox guarding the henhouse. The merged entity would have no incentive to control costs. The market power is evidenced by CVS and Aetna's ability to engage in past exclusionary and deceptive acts that harm pharmacies and patient access. And as a business-healthcare enterprise, it is likely to be beyond the reach of state insurance regulators.

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<sup>1</sup> Council of Economic Advisers, *Reforming Biopharmaceutical Pricing t Home and Abroad*, Feb. 2018, available at <https://www.whitehouse.gov/wp-content/uploads/2017/11/CEA-Rx-White-Paper-Final2.pdf>. ("White House Paper")

<sup>2</sup> See CVS Health, available at <https://cvshealth.com/about/facts-and-company-information>. Also, testimony of Mark Merritt, Pharmaceutical Care Management Association, before the U.S. House of Representatives Energy and Commerce Committee Subcommittee on Health, "Examining the Drug Supply Chain," Dec 13, 2012.

<sup>3</sup> White House Paper.

## **Aetna**

As a Medicare Part D provider, Aetna was sanctioned by the Centers for Medicare & Medicaid Services (“CMS”) in 2010 and again in 2015 for ***unclear messaging to seniors*** about which pharmacies were in Aetna’s preferred network. In some cases, seniors correctly changed their pharmacy provider, but in other cases, seniors were forced to give up their time-tested relationships with a trusted local pharmacist. Aetna’s failures exposed Medicare beneficiaries to unnecessary risk, jeopardizing their access to prescription medications and the ongoing support for adherence.

Also in the Medicare arena, the 2018 plan year marked the second consecutive year in which Aetna denied many community pharmacies from participating in their Part D networks as “preferred” network pharmacies. This designation means lower co-pays for beneficiaries. Pharmacies experience the exclusion as a decrease in prescription volume that negatively affects their bottom line.

## **Divestment of Aetna’s Medicare Part D plans Does Not Resolve Competition Problems**

It is important to note that when Aetna sells its Part D business to WellCare Health Plans, Inc., as required by the DOJ, the prescription benefit will, in fact, go to CVS Caremark which is the PBM that processes for WellCare’s. This means that money will flow through different channels, but the result will be the same. CVS Health retains access to patient data and will be in control of multiple revenue streams. In the new vertically integrated business model, it is impossible to control conflicts of interest. The rights of pharmacies in networks managed by CVS Health and the rights of patients to access medications from a pharmacy they choose will fall by the wayside.

Besides the continuing vertical type problems, we do not see how the merger would resolve competition issues in Part D individual plans because WellCare is not likely to compete aggressively against CVS Silverscript given its cozy ongoing relationship. Also, it will be difficult for WellCare to preserve the membership that it is acquiring in upcoming enrollment periods.

## **CVS Caremark**

Evidence of CVS’ market power is its ability to engage in exclusive and deceptive acts because of the lack of PBM regulation. After the transaction, because CVS/Aetna’s incentive will change and it will have an increased ability to steer Aetna insureds away from community pharmacies. Again, the following bad acts indicate that CVS already has market power because in a competitive market, CVS will not be able to engage in the following anticompetitive activities.

CVS Health has come under fire for its role as a Medicaid managed care PBM. A report released in August, 2018 by the Ohio State Auditor Dave Yost found that CVS Caremark charged health plans \$208 million more

than CVS Caremark paid pharmacies for the prescription drugs.<sup>4</sup> Pennsylvania released a similar finding last week.<sup>5</sup>

CVS Caremark has also come under scrutiny by insurance regulators. The Kentucky Department of Insurance issued a \$1.5 million civil penalty against pharmacy benefit manager CVS Caremark for violations related to pharmacy reimbursements. Insurance authorities placed the CVS Caremark PBM license on probation for one year citing 454 violations related to reimbursement claim denials and 38 additional violations for “inaccurate or inconsistent information” in mandatory reports.

Arkansas authorities accused CVS Caremark of billing Medicaid managed care plans twice as much (or more) compared to what their (CVS) pharmacies got paid. They also charged that data from fully-insured commercial health plans showed that CVS Caremark paid itself over \$60 on average more per prescription than the PBM paid community pharmacies.<sup>6</sup>

In each of these cases, reimbursements are funded off the backs of consumers, taxpayers and other premium-payers.

A public website for a CVS Health-sponsored federal employee plan reveals that CVS Caremark sets prescription prices higher for itself and other large national chains than for smaller regional chains and local independent pharmacies in its network. Such differential reimbursement policies squeeze out local pharmacies and those that remain open are in weakened financial health. This public website is no longer available the consumer must now create a personal log-in to access their prescription pricing.

In the fall of 2017, CVS Caremark brought community pharmacies to their knees when it drastically reduced reimbursements for generic prescriptions in states along the East Coast. The sudden drop affected access to some medications as pharmacies were unable to replenish inventories. In New York, CVS Caremark is the PBM for a significant number of Medicaid managed care plans particularly in the New York City area, alarming state Medicaid officials. Clearly the action of one dominant PBM servicing many health plans affected pharmacy operations and directly impacted Medicaid patients, a medically fragile patient population. It is worth mentioning here that pharmacies have a remedy in NYS Public Health Law 280a which created a process by which a pharmacy could appeal a reimbursement that was below cost. But CVS Caremark ignored the law, flatly denying hundreds of appeals and ignoring others on the basis of technicalities.

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<sup>4</sup> <https://ohioauditor.gov/news/pressreleases/Details/5042>

<sup>5</sup> <https://pittsburgh.cbslocal.com/video/category/spoken-word-kdkatv/3992446-auditor-general-urging-crackdown-on-pharmacy-benefit-managers/>

<sup>6</sup> Linette Lopez. “What CVS is doing to mom-and-pop pharmacies in the US will make your blood boil.” Business Insider. March 30, 2018.

CVS Caremark went even further. Pharmacies began receiving letters from CVS Health offering to buy them out due to “declining reimbursements.”<sup>7</sup>

Recently amended contracts now require pharmacies to meet a specific generic effective rate (GER) or generic dispensing rate (GDR). These performance metrics are an example of onerous contract terms that pharmacies are forced to accept in order to remain in a PBM network, and they are unreasonable. Pharmacies do not issue prescriptions and have no authority to change prescribed brand medications to generics. GERs and GDRs serve a valuable purpose for PBMs such as Caremark, however. They are the technicality by which Caremark and other PBMs by-pass “Maximum Allowable Cost” laws and serve as the mechanism by which additional dollars can be extracted from community pharmacies in their networks.

Patients who routinely choose to obtain their medications from a local participating pharmacy report receiving phone calls from Caremark representatives pressuring them to opt into the mail order programs offered by CVS. Although receiving medications by mail works for some, it is not a good fit for all. Many patients rely on the ongoing support of a local pharmacist to help them manage their medications treating chronic medical conditions so they can maintain their independence. For those who have difficulty communicating by phone or using the internet, mail order is a bad choice. The problem for pharmacists is that some customers/patients will continue to visit their local pharmacies to ask questions about their prescription drugs that they may be receiving from CVS mail order. In other words, CVS is free-riding on local community pharmacists who are actually continuing to service CVS patients that are receiving medications from CVS.

### **CVS Caremark limits access to medications by controlling the formulary.**

Formulary exclusion lists are a PBM-industry standard. By reserving the right to exclude certain medications from the formulary, PBMs gain leverage to negotiate steeper rebates and discounts from drug manufacturers. These discounts, however, are not always passed on to employers, health insurers, and patients. For patients, however, formulary exclusions can mean being denied coverage for a medically necessary and doctor-prescribed treatment. In 2017, 37% of denials for treatment for chronic illnesses were due to formulary exclusions.<sup>8</sup>

Since 2012, CVS/Caremark more than quadrupled the number of treatments it does not cover, from 38 to 183. It was the first PBM to exclude some cancer medications.<sup>9</sup> Other market-dominant PBMs soon followed. On October 1, 2018, CVS/Caremark released its latest list of formulary exclusions for 2019 that includes a number of injectable medications impacting diabetic and behavioral health patients who ironically are most in need of ongoing counseling and support from local pharmacists.

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<sup>7</sup> “CVS/Aetna: State Regulators Urged to Investigate CVS Caremark Reimbursement Cuts, Solicitation Letters, as Part of Aetna Review. The Capitol Forum. January 12, 2018.

<sup>8</sup> The Doctor Patient Rights Project. The De-List: How Formulary Exclusion Lists Deny Patients Access to Essential Care. December, 2012.

<sup>9</sup> Community Oncology Alliance: The Real-Life Patient Impact of Pharmacy Benefit Managers. April, 2017: “Delay, Waste, and Cancer Treatment Obstacles; May, 2017: “Real Horror Stories of How PBMs Hurt Patient Care; September, 2017: “Bureaucracy, Deadly Delays, and Apathy.”

### **Will CVS Health-Aetna lower costs?**

The merged parties state that their improved corporate entity will improve efficiency and yield significant savings, but we have not seen any explanation of how the savings will be realized by patients and payors. The three largest PBMs have made that claim repeatedly, yet patients' out-of-pocket costs continue to increase, and premiums have too.

Will more patients be forced into mandatory mail order programs? It's a common misconception that mail order lowers drug costs for consumers but evidence demonstrates that mail order pharmacies consistently dispense costlier brand-name drugs and fewer generics than retail pharmacies. At the end of the day, a shift to more mail order will lower the rate of generic dispensing, ultimately increasing overall drug costs. In comparison, community pharmacies dispense generics 88% of the time. It is also worth noting that automatic shipments from mail pharmacies generate significant volumes of waste. In the most recent DEA-sponsored national drug take-back day, October 27, 2018, Americans discarded 457.12 tons of unused, unneeded medications. Although precise documentation as to the source of discarded medications is not possible due to patient confidentiality concerns, mail pharmacies routinely ship in 90-day supplies and report difficulty stopping automatic shipments.

### **The Medical Loss Ratio raises another concern**

In an entity where the pharmacy, the PBM and health plan are under single ownership, where is the drug cost calculated? When CVS purchases the drug? When the PBM reimburses CVS for the drug? When Aetna pays the PBM for the drug? Drug costs are a legitimate component of reportable medical expenses when insurance administrators calculate the "medical loss ratio." How responsive will the CVS Health-Aetna corporation be to insurance regulators in the states?

### **Conclusion**

For all of the reasons above, the Antitrust Division should reconsider its decision, withdraw its settlement, and revise it to address the vertical concerns raised by the transaction.

Sincerely,



Debra Barber, RPh  
President

