COMMUNITY ONCOLOGY ALLIANCE
Innovating and Advocating for Community Cancer Care

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Via Overnight Delivery and Email

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Chief, Healthcare and Consumer Products Section,
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Department of Justice
450 Fifth Street NW, Suite 4100
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RE: United States of America v. CVS Health Corporation and Aetna Inc.
Dkt. No.: 1:18-cv-02340

Dear Mr. Mucchetti:

The Community Oncology Alliance ("COA") submits this letter on behalf of its oncologist-members and, more critically, the patients to whom its members provide cancer care. COA writes in opposition to the proposed settlement of *United States of America v. CVS Health Corporation and Aetna Inc.*, Dkt. No.: 1:18-cv-02340 ("*U.S. v. CVS and Aetna*"). The Department of Justice's greenlighting of the CVS-Aetna merger in exchange for Aetna's divestiture of its standalone individual Medicare Part D prescription drug plans ("individual PDPs") is insufficient to stem the foreseeable tide of destructive anti-competitive consequences that will flow therefrom, compounding issues already plaguing the healthcare system. Of primary import to COA are those anti-competitive market forces that will create further (and wholly unnecessary) complications and delay for cancer patients, many of whom are Medicare beneficiaries, attempting to secure the medications they need to survive and live productive, meaningful lives. Pharmacy Benefits Managers ("PBMs"), especially when combined with insurers, can interrupt the relationship between oncologists and their patients.

PBMs already regularly create such complications and delay, by wresting control of the dispensing process from independent oncology practices and steering patients to PBM-owned specialty and mail order pharmacies. The "steering" of prescriptions from independent oncology practices to PBMs causes substantial disruptions in the physician-patient relationship (for both private and Medicare patients) and lessens the quality of care. Such disruption is inextricably intertwined with PBMs' vertically integrated business model. The merger of CVS Health and Aetna combines the nation's largest PBM, which owns one of the largest Medicare Prescription Drug Programs (SilverScript Insurance Company) and largest Specialty Pharmacies (CVS Specialty) with one of the nation's largest insurance carriers (Aetna). This combination will substantially magnify the PBM-business-model's negative impact on an already broken healthcare system, causing the government's already untenable drug spend to exponentially increase, and patients to pay artificially inflated copayments. We urge the DOJ to rethink and further vet the proposed deal

Recent Events Portend Ominous Changes to Come—Audit Fees. The newly combined CVS/Aetna company has already proven itself untrustworthy and has laid bare the true aim of the merger – total market domination, without regard for patient welfare or the betterment of the healthcare system. Specifically, on October 10, 2018 – *the very same day on which the DOJ gave the merger its blessing* – CVS/Caremark modified its Provider Manual (by way of a "2019 Provider Manual Supplement") by increasing the already legally dubious "audit chargeback" fee by 33%. This increased "audit fee," incidentally, is not rationally related to the actual cost of provider audits in most cases but is rather a thinly-disguised vehicle to tax pharmacies and independent oncology practices within the PBM's pharmacy network. This "audit fee" increases CVS Health's profits, is not turned over to Plan Sponsors and weakens Providers within PBM pharmacy networks. While the timing of the increase in the "audit fee" is suspect and plainly indicative of the CVS/Aetna entity's designs for the nation's healthcare market, it is also not unusual for a PBM Provider Manual. PBM provider manuals, nearly without exception, are unmodifiable contracts of adhesion, filled to the brim with onerous terms intended to under-reimburse and penalize independent oncology practices and pharmacies. In short, the Aetna/CVS merger was not designed to improve efficiencies in the administration of healthcare – it was principally designed, like the PBM Provider Manual, to shift dollars from independent providers to its wholly-owned pharmacies – a process that will drastically weaken competition.

CVS/Aetna will Continue to Block Independent Oncology Practices from Caremark's Networks. One of the strongest tools in the arsenal of a vertically integrated healthcare behemoth is denying competitors from "network access". All Medicare Part D payments are made to providers through PBMs. Currently, only five PBMs control network access for more than 80% of the covered lives in the United States. With only five PBMs, network access to each is critical for pharmacies and dispensing healthcare providers. The power of PBMs to restrict the classes of "in-network" providers will thus diminish patient care and the healthcare landscape. Moreover, this is inconsistent with the government's growing efforts to employ initiatives such as Value Based Care programs in the federal healthcare system to lower patient costs, as patient steering from independent oncology practices to PBM-owned specialty pharmacies will ultimately increase both the medical and drug spend to the government.

The impact of PBM action to potentially limit network access to independent oncology practices is even more pronounced in the specialty drug marketplace, where such practices frequently treat Medicare cancer patients. More than two-thirds of the growth in overall medicine spending is attributable to specialty medicine. In 2015, 37% of the total United States spending on drugs was attributed to specialty medications, and this year, specialty medications are projected to account for 50% of total drug spend. Independent physician practices comprise about 46% of the specialty medical spend, and, according to a 2014 study conducted by the University of Utah, 14% of all prescriptions purchased by participating consumers were dispensed directly by a physician. In addition, the cancer prevalence in the Medicare population is much higher, at nearly 9% versus less than 1% in the commercial population. PBMs have taken a variety of actions aimed at capturing increased specialty pharmacy business and the profits associated with specialty drug spending. All major PBMs, including Prime Therapeutics, OptumRx, Express Scripts and CVS Caremark, have acquired or launched their own specialty pharmacies to gain market share in the growing specialty drug space. CVS Caremark recently announced that it has opened a new 112,000 square foot specialty pharmacy facility in Orlando, in order to handle its continually increasing specialty drug volume. These recent efforts are positive for shareholders, but negative for physicians and Medicare patients. Oncology patients will have less choice after the merger.

It is well-documented that CVS began a trend two years ago that other PBMs have unfortunately followed, in which they have sought to block independent oncology practices from their pharmacy networks. Oncologists dispense oral oncolytics in competition with CVS's crown jewel—CVS Specialty. More vexing for CVS still, independent oncology practices often have access to "limited distribution drugs" that traditional specialty pharmacies typically cannot obtain, heightening its incentive to interfere with physicians' ability to dispense to protect and expand CVS Specialty. CVS has been hostile to in-office dispensing in the oncology-sphere, even though, for purposes of

administering and monitoring the effects oral oncolytics, in-office dispensing is plainly optimal for patient care. See, e.g., https://www.communityoncology.org/wp-content/uploads/sites/20/2018/08/PBMs_Physician_Dispensing-WhitePaper_COA_FL.pdf. Working in tandem with PBMs, insurance carriers increasingly require their plan enrollees to obtain cancer drugs through specific, PBM-owned specialty pharmacies, which often ship the medications weeks or months later than their physicians could have dispensed, resulting in delayed care. With oncology patients, care delayed is care denied.

As set forth in greater detail below, COA-members have witnessed, firsthand, how such delays can severely impact a cancer patient's treatment and health, arguably leading in some cases to avoidable death for lack of timely administration of life-saving medications. Plainly, the most efficient, ethical and clinically effective means of dispensing medications for cancer patients is to permit oncologists to dispense using their own in-office pharmacies at the point of care (i.e., the oncologist's in-office pharmacy or in-office dispensing). At this site of care, dispensing may take place immediately and the provider, who has access to both the patient's electronic health record and dispensing records, is in the best position to ensure patient compliance with their drug regimen and provide complete coordination of care. But efficiency and optimized patient outcomes are not priority for PBMs; maximizing profit is their sole guiding principle.

COA is in a Strong Position to Comment on Patient Care for a Vulnerable Cancer Population that is Often Medicare Beneficiaries. In lieu of further detailing the legal and economic reasons justifying blocking the merger – reasons already provided and analyzed by other interested parties– COA wishes to provide the DOJ with some concrete, real-world examples of the sorts of patient abuses, including ***cancer patient*** abuses. Patient stories regarding PBM behavior paint a disturbing trend that will only be enhanced by the merger. One member recounts how a young husband, diagnosed with advanced melanoma with brain metastases and given a grim prognosis, believed, for a brief time, that his luck may have turned when his doctor had identified a promising new drug that had the potential to significantly prolong his life. The oncologist-COA-member was equipped with an in-office pharmacy where the medication could have been lawfully and swiftly dispensed to the patient; however, the patient's PBM required him to purchase his medication from one of their own mail-order pharmacies. Even though the oncologist-member immediately faxed to the PBM all of the necessary information for receiving prior authorization, it took ten days before such authorization was issued. One week later, however, the drug had still not arrived, and, upon inquiry, the patient was advised that the drug would not ship until he had first remitted a $1,000 co-pay, an amount he was unable to afford. The patient's wife was then forced to work to arrange for co-pay assistance on her own, as the patient at this point had been admitted to the ICU. After several days of jumping through difficult administrative hoops, his wife succeeded in securing approval for co-pay assistance and forwarded the information on to the PBM's pharmacy, which then, ***finally***, mailed the drug to the patient. By the time the drug had arrived, however, the patient could no longer swallow pills and, tragically, he died shortly thereafter. Had the patient not been trapped by his carrier and its affiliated PBM, and his physician had been able to dispense at the point of care, this tragedy could very well have been avoided. COA Members are able to dispense the medications, often at the site of care, but when the Insurer is owned by the PBM and the PBM owns a specialty pharmacy, deals are cut to make the PBM-owned specialty pharmacy the "exclusive" provider.

Another COA member recounts his experience treating a 73-year old husband, who had been battling metastatic non-small cell lung cancer for some time, when his oncologist identified and prescribed a new medication that the FDA had recently approved for similar cases. Even though the oncologist was ready and able to dispense the medication from his in-office pharmacy, the patient's plan would not allow it – it could only be filled by a specialty pharmacy owned by the PBM with which his carrier had contracted. On November 13, the oncologist submitted a request for prior authorization to the PBM. The PBM denied the request for a clinically nonsensical reason – it could not approve it until it had reviewed the patient's blood tests for jaundice. Knowing that the PBM game must be played for the sake of the patient's health, the request was re-submitted with the (clinically unnecessary) jaundice

blood test results, and then doctor and patient waited, and waited – ***for weeks***, despite repeated status calls by the oncologist to the patient's plan. On December 4, as the oncologist waited on hold with the carrier yet again, the patient's family called to advise him that the patient had passed. The economic incentive for PBMs to steer these patients to the PBM-owned specialty pharmacies is strong and the PBMs wield too much power to responsibly maintain focus on patient care.

The merger will create a vertically integrated healthcare entity of enormous power, and it will inevitably exercise that power as would any other PBM, by further reducing cancer patients' pharmacy benefits coverage options so as to render them captive to the entity's wholly-owned pharmacies, and continue to substantially interfere with the oncologist-patient relationship in an effort to stamp out independent-oncology-practice-based competition.

For all of these reasons, we respectfully request that the DOJ reconsider its approval of the merger.

Sincerely,

Jeffrey Vacirca, MD, FACP
President

C: Hon. Richard J. Leon, U.S.D.J.