AHF AIDS HEALTHCARE FOUNDATION

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RE: Tunney Act Comments of the AIDS Healthcare Foundation, Inc. in *United States v. CVS Health Corporation and Aetna, Inc.*, Case No. 1:18-cv-02340

Dear Mr. Mucchetti:

The AIDS Healthcare Foundation ("AHF") submits the following comments to the Department of Justice Antitrust Division (the "Division") pursuant to Section 2(b) of the Antitrust Procedures and Penalties Act (the "Tunney Act"), 15 U.S.C. § 16(b), concerning the $69 billion acquisition of Aetna Inc. by CVS Health.

AHF is the largest non-profit provider of care and treatment to people with HIV and AIDS in the world, serving over one million patients in 43 countries. In the United States, AHF has healthcare centers and pharmacies in 15 states, and has Medicaid and Medicare managed care plans in California, Florida and Georgia. Established in 1987, AHF's mission is to provide cutting-edge medicine and advocacy for individuals living with HIV and AIDS. For every dollar earned by AHF Pharmacies, 96 cents goes to patient care, assisting communities afflicted with HIV and AIDS.

Representing a special needs population, AHF is profoundly troubled by the conglomeration of the health care industry, especially when the payors, pharmacy benefits managers ("PBMs"), and providers become one and the same. AHF believes that the Proposed Final Judgment is not sufficient to protect consumers or competition generally. The merger will lessen competition in the health care provider, PBM, and pharmacy markets – effects of the merger that the Division failed to even address in its Complaint and Proposed Final Judgment.

A. Public Interest Standard

The Tunney Act provides for the Court to make a determination that the entry of the Proposed Final Judgment is in the public interest. Specifically, the Act requires the court to consider the following enumerated factors:

> (A) the competitive impact of such judgment, including termination of alleged violations, provisions for enforcement and modification, duration of relief sought, anticipated effects of alternative remedies actually considered, whether its terms are ambiguous, *and any other competitive considerations bearing upon the adequacy of such judgment that the court deems necessary to a determination of whether the consent judgment is in the public interest*; and
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> (B) the impact of entry of such judgment upon competition in the relevant market or markets, upon the public generally and individuals alleging specific injury from the violations set forth in the complaint including consideration of the public benefit, if any, to be derived from a determination of the issues at trial.

15 U.S.C. § 16(e)(1)(A) and (B) (emphasis added). In both the Competitive Impact Statement and the December 2, 2018, "Status Report on Merger Integration," the Division claims that the Court's role in determining whether the proposed remedy is in the public interest is necessarily a limited and narrow one, and that the government is entitled to broad discretion to settle with the defendant "within the reaches of the public interest."[1] But the Court's discretion in making the public interest determination is much broader that the Division claims.

In passing the Tunney Act, Congress rejected the idea that courts must defer broadly to the government's proposed consent decrees when determining whether such decrees are in the public interest. Courts cannot "unquestionably accept a proffered decree as long as it somehow, and however inadequately, deals with the antitrust and other public policy problems implicated in the lawsuit. To do so would be to revert to the 'rubber stamp' role which was at the crux of the congressional concerns when the Tunney Act became law."[2] Thus, Judge Leon was correct when he stated at a recent hearing that the Court is "not a rubber stamp" and that the proceedings to determine whether the Proposed Final Judgment will be approved is not "just some rubber-stamp operation."[3]

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[1] Competitive Impact Statement, *United States v. CVS Health and Aetna Inc.*, Case No. 18-cv-02340 (D.D.C. 2018), at 14; Status Report on Merger Integration, *CVS Health and Aetna Inc.*, Case No. 18-cv-02340 at 3.

[2] 150 Cong. Rec. S3617 (Apr. 2, 2004) (quoting *United States v. AT&T*, 552 F. Supp. 131, 151 (D.D.C. 1982)).

[3] Hearing Transcript at 16-17 (Nov. 29, 2018).

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In 2004, Congress amended the Tunney Act after determining that subsequent case law was "contrary to the intent of the Tunney Act and effectively strips the courts of the ability to engage in meaningful review of antitrust settlements."[4] First, Congress mandated the court to take the enumerated factors above (15 U.S.C. § 16(e)(1)(A) and (B)) into account in an analysis of the consent decree. Second, Congress enacted another enumerated factor – requiring the Court to consider "the impact of the entry of such judgment upon competition in the relevant market or markets."[5]

The intent of the 2004 Amendments was "to explicitly restate the original and intended role of the District courts in this process by mandating that the court make an independent judgment based on" the enumerated factors cited above.[6] Thus, as Judge Leon recognized, the Court's role is vital here, to "deter and prevent settlements…which were plainly inadequate…[by giving] real scrutiny…[and] carefully review[ing] antitrust consent decrees to ensure that they are in the public interest."[7]

Consistent with the Court's important role in the Tunney Act process, Judge Leon has raised concerns that the Division's complaint is drafted too narrowly, in that it "raises anti-competitive concerns about one-tenth of one percent of this $69 billion deal."[8] AHF shares those concerns. The Division's complaint and Proposed Final Judgment focus exclusively on the Medicare Part D market, while ignoring other markets in which CVS and Aetna both operate, and in which the merger will undoubtedly have harmful anticompetitive effects.

B. Effects in Health Care Provider Markets

The merged entity will have the financial incentive to force Aetna subscribers to utilize CVS Minute Clinics as opposed to other health care providers. Over the past few years, there has been a rise in the number of CVS Minute Clinics, especially within CVS retail establishments. There are currently 1,100 CVS Minute Clinics across 33 states. CVS recently announced that its

[4] 150 Cong. Rec. S3615 (Apr. 2, 2004).

[5] *Id.*

[6] *Id.*

[7] 150 Cong. Rec. S3616 (Apr. 2, 2004).

[8] Hearing Transcript at 6-7 (Dec. 3, 2018)

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immediate goal is to grow that number to 1,500 clinics, and its longer-term goal is for half of all Americans to live within 10 miles of a CVS Minute Clinic.[9] Minute clinics replace fundamental elements of the patient-physician relationship with "cookie cutter" treatment administrated by non-physicians. The combination of CVS and Aetna will have the effect of directing Aetna patients to a CVS Minute Clinic instead of the patient's chosen physician.

Where the insurance company (which in this case would be owned by CVS post-merger) is determining where an insured can go to receive services, there is a risk that such determinations will be made for financial reasons rather than medical ones. This can be dangerous for the health of the insured. AHF runs numerous clinics focused on the treatment of individuals living with HIV or AIDS, and thus understands that the treatment for such a patient must be comprehensive and under the watchful eye of the patient's primary care physician/HIV specialist. Even the most "routine" services are not routine for a person with HIV. For example, a CVS Minute Clinic delivering a flu shot to a person with HIV is risking the health of a person whose immune system might be vulnerable to a partial live virus vaccine.

Additionally, because of the prevalence of CVS Minute Clinics across the country, coupled with CVS's goal to expand its minute clinic presence, the combination of CVS and Aetna will create an unfair competitive advantage for CVS. CVS will have the ability to foreclose the opportunity for other medical providers to participate in Aetna insurance networks, limiting consumer choice and likely raising costs to consumers as well as competing providers.[10]

In recognition of these real and legitimate concerns, at least one state, Georgia, approved CVS's acquisition of Aetna only on the condition, among others, that the merged entity must invite non-CVS health care providers to join its networks, and must set the same criteria for each of its providers. The merged entity is also required to allow Georgia residents to use any health care provider, in or out of network, if that provider accepts the same conditions as those within the network.

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[9] CVS Health, "What's Next for MinuteClinic," available at https://cvshealth.com/thought-leadership/whats-next-for-minuteclinic.

[10] *See* Letter to Hon. Katherine L. Wade, Commissioner, Connecticut Insurance Department from Maria T. Vullo, Superintended, New York Department of Financial Services at 3 (September 17, 2018) (expressing concern that the combination of CVS and Aetna, through the use of minute-clinics "creates significant concerns for consumer choice and cost, as well as employment in the health care system overall.").

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C. Effects in the PBM Market

CVS's acquisition of Aetna removes a potential competitor from the PBM market, Aetna, further securing CVS's dominant position as a PBM with significant market share. The current PBM market is ultra-concentrated, with the top three PBMs, led by CVS, controlling approximately 75% of the market.[11] PBMs are middle-men that operate at the intersection of drug manufacturers, payors and pharmacies. PBMs negotiate prices with drug companies, receive rebates from the drug companies to place specific drugs on formularies, provide drug benefit services for insurers, and establish pharmacy networks for the insured beneficiaries to utilize. However, the PBM market suffers from a lack of transparency and an absence of meaningful regulation. This is so despite the substantial impact PBMs have on health care costs in the United States.

The loss of Aetna as a potential competitor in the PBM market will all but cement CVS's dominant position. Aetna is one of the few insurers with the resources and expertise to enter and compete in the highly concentrated PBM market. By removing a significant potential competitor, CVS's acquisition of Aetna makes it substantially more difficult for new potential competitors to enter the PBM market and compete effectively.

D. Effects in the Pharmacy Market

CVS is a dominant pharmacy and PBM. The addition of Aetna will make it a dominant health insurer as well. The combination across numerous channels of the health care continuum provides significant incentives to depress competition, particularly at the pharmacy level. Roughly half of CVS's $184 billion in 2017 revenue was through its pharmacy services.[12] Thus, CVS clearly has an incentive to continue to sustain and grow its pharmacy business. Currently, there is no obvious incentive for Aetna to favor CVS pharmacies for its insureds. However, post-merger, CVS will have the incentive and the ability to shift all Aetna subscribers to CVS pharmacies in local markets throughout the country, thus foreclosing independent pharmacies like AHF from servicing Aetna subscribers in those markets. In markets where Aetna has a

[11] "The Big Three Dominated Again in 2017," Pembroke Consulting (March 5, 2018), available at http://drugchannelsinstitute.com/files/PBMI-PBM_Outlook-Drug_Channels-Fein-Mar2018-Handouts.pdf.

[12] Adam Fein, "The Top 15 US Pharmacies of 2017," Drug Channels (February 21, 2018), available at, https://www.drugchannels.net/2018/02/the-top-15-us-pharmacies-of-2017-market.html.

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strong presence—which are many—such customer foreclosure would have significant anticompetitive effects, not only on independent pharmacies like AHF but also on pharmacy competition in general. Independent pharmacies will be forced to either raise drug prices or exit the market altogether. Either way, consumers will suffer.

This is not a theoretical concern. Large PBMs affiliated with insurance companies have demonstrated the ability to force patients to obtain their medications only at such captive pharmacies, thus denying patients the freedom of choice of pharmacy providers. There are other ways in which the merger will embolden CVS to take actions that will raise pharmacy costs for health plans and consumers. For example, CVS, combined with Aetna, may force an increase in mandatory utilization of mail order pharmacy services to obtain medication.[13] Mandatory mail order is particularly dangerous for individuals living with HIV, as the loss of direct access to a pharmacist complicates the patient's treatment regimen. Control of the virus is dependent upon rigid adherence to a drug treatment plan, and such adherence is dependent upon routine contact with multiple touch points in the health care delivery system. The pharmacist is one of those key touch points--mail order delivery distances the patient from that touch point. CVS's acquisition of Aetna will increase the captive population to whom CVS can force the use of mail order services, denying this population the benefits of direct access to a pharmacist.

Further, a post-merger CVS, with the inclusion of Aetna's 22 million lives, will have the leverage and incentive to use increasingly aggressive tactics to narrow its networks to exclude small and specialty pharmacies. For example, a combined CVS/Aetna will be able to use its increased leverage to exclude competing pharmacies from providing HIV/AIDS medication to individuals enrolled in states' AIDS Drug Assistance Programs ("ADAP"). ADAP is a federally-funded, state-run, prescription medication program for low-income uninsured or underinsured people living with HIV/AIDS. CVS is already the sole-source provider for the ADAPs in Illinois and Ohio, affecting thousands of uninsured individuals living with HIV/AIDS. The merger will only empower CVS/Aetna to exclude competing pharmacies from other states' ADAPs. CVS/Aetna will also have the incentive and ability to take anticompetitive measures such as driving down reimbursement rates and dispensing fees to uncompetitive levels. While such

[13] In 2014, Aetna subscribers brought a lawsuit alleging that a proposed Aetna mandatory mail order HIV and AIDS prescription drug plan threatened patients' health and privacy. Aetna settled the lawsuit, allowing affected subscribers to opt-out of any mail order program. *See Doe v. Aetna Inc., et al.*, Case No. 14-cv-02986 (S.D.Cal. 2014).

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conduct is already happening, for example in Arkansas, Ohio and Pennsylvania,[14] the merger will make it worse.

Moreover, the merger will provide incentives for CVS to implement additional fees on network pharmacies, in efforts to extract more money from its competitors or drive them out of the market. One specific example is Direct and Indirect Remuneration ("DIR") fees, or "performance fees." PBMs impose such fees on pharmacies, requiring them to meet certain vague performance standards that in many cases do not apply to the pharmacies. If the pharmacies do not meet certain metrics, the PBMs claw back these fees out of reimbursement already paid to the pharmacies - often months or even a year after the medication was dispensed; if the pharmacies do meet certain metrics, less fees are clawed back. For pharmacies such as AHF that concentrate on the treatment of HIV and AIDS, such mandated performance metrics simply do not apply, but the PBMs impose the fees anyway.

In recent proposed rule changes, the Centers for Medicare and Medicaid Services recognizes that such conduct by PBMs can lead to anticompetitive outcomes:

> Finally, the one-sided nature of the pharmacy payment arrangements that currently exist also creates competition concerns by discouraging independent pharmacies from

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[14] Arkansas Attorney General Leslie Rutledge is currently investigating a scheme in which CVS is alleged to be providing unprofitable reimbursement arrangements to independent pharmacies, rendering the pharmacies unable to remain in operation, and then offering to buy out these pharmacies for pennies on the dollar. The Arkansas Attorney General has announced that it is investigating whether such practices are in violation of the state's Deceptive Trade Practices Act and other applicable laws. See *Rutledge to Investigate Reimbursement Rates From CVS Caremark*, Press Release (February 8, 2018), available at https://arkansasag.gov/media-center/news-releases/rutledge-to-investigate-reimbursement-rates-from-cvs-caremark.

The Ohio Attorney General's office is conducting investigations into PBMs' conduct towards those doing business with Ohio agencies. It has stated that PBMs are "on notice that their conduct is being heavily scrutinized, and any action that can be taken and proven in court will be filed to protect Ohio taxpayers and the millions of Ohioans who rely on the pharmacy benefits provided." *See* Attorney General Mike DeWine Statement on PBM Investigation (July 23, 2018), available at https://www.ohioattorneygeneral.gov/Media/News-Releases/July-2018-%281%29/Attorney-General-Mike-DeWine-Statement-on-PBM-Inve.

The Pennsylvania Auditor General, Eugene DePasquale, is conducting an investigation into PBMs' "spread pricing"—the difference between what PBMs charge state the Medicaid program and what they pay pharmacies for services to Medicaid beneficiaries. Specific concerns over depressed pharmacy reimbursements by CVS are a focus of the investigation. *See* Catherine Dunn, *PA Auditor General Wants to Take a Whack at Firms That Negotiate Drug Benefits for the Medicaid Program*, Philadelphia Inquirer (December 11, 2018), available at http://www2.philly.com/business/pbms-pennsylvania-medicaid-drug-prices-cvs-auditor-general-20181211.html.

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> participating in a plan's network and thereby increasing market share for the sponsors' or PBMs' own pharmacies. Part D is a market-based approach to delivery of prescription drug benefits, and relies on healthy market competition. Thus, adopting policies that promote competition is an important and relevant consideration in protecting Medicare beneficiaries and the Medicare trust fund from unwarranted costs. Market competition is best achieved when a wide variety of pharmacies are able to compete in the market for selective contracting with plan sponsors and PBMs.[15]

Finally, because the Court must determine whether entry of the Proposed Final Judgment is in the public interest, it is appropriate for the Court to consider how CVS has conducted itself with its current population, understanding that the merger will direct even more patients to CVS pharmacies. Thus, the Court should take note that CVS is currently defending a lawsuit over its revealing the HIV-positive status of up to 6,000 Ohioans through a mailing concerning such prescriptions.[16] This follows a 2017 breach by Aetna that revealed the HIV status of patients across several states.[17] The Court should also take note of the numerous instances over the last decade in which CVS has engaged in various forms of misconduct, which the government has investigated, and for which CVS has paid the government millions of dollars.[18]

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[15] Department of Health and Human Services, Centers for Medicare & Medicaid Services, *Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out-of-Pocket Expenses* (2018-25945) at 92, available at https://s3.amazonaws.com/public-inspection.federalregister.gov/2018-25945.pdf#page=82.

[16] *See Doe One et al. v. CVS Health Corp. et al.*, Case No. 18-cv-00238 (S.D.Ohio 2018).

[17] Several state Attorneys General, including but not limited to Connecticut, New Jersey, New York, and Washington, recovered money from Aetna in the form of civil penalties for this breach. Additionally, Aetna settled a private lawsuit stemming from the same conduct for $17 million. *See Beckett v. Aetna Inc, et al.*, Case No. 17-cv-03864 (E.D.Pa. 2017).

[18] *See, e.g.*:

- June 28, 2018: CVS agreed to pay $1.5 million to the United States to resolve allegations by the Department of Justice of a violation of the federal Controlled Substances Act that several stores failed to timely report the loss of controlled substances, contributing to the opioid epidemic;
- July 11, 2017: CVS paid $5 million to the United States to resolve federal Controlled Substance Act allegations by the Department of Justice that its pharmacies failed to keep and maintain accurate records of controlled substances;

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In short, CVS's increased leverage through the merger will embolden the merged company to increase costs on pharmacies such as AHF and drive out competition – leading to higher drug prices and increased privacy and safety concerns, to the detriment of consumers and health plans.

E. Conclusion

CVS's acquisition of Aetna will cause significant anticompetitive effects that go well beyond the Division's narrow complaint. While the Court is statutorily required to review the Division's complaint and Proposed Final Judgment and make a determination if such remedy is in the public interest, when the complaint is drafted so narrowly "as to make a mockery" of the Court's power, [19] the Court should consider the other competitive problems resulting from the proposed merger. CVS will use the increased leverage from its purchase of Aetna and Aetna's 22

- October 17, 2016: CVS subsidiary agreed to a $28 million settlement with the Department of Justice to resolve allegations that it solicited and received kickbacks from a pharmaceutical manufacturer in exchange for promoting the prescription drug, Depakote;
- June 30, 2016: CVS agreed to pay $3.5 million to the United States to resolve allegations by the Department of Justice that fifty (50) of its stores violated the Controlled Substance Act by filling forged prescriptions for addictive painkillers more than 500 times between 2011 and 2014;
- February 12, 2016: CVS agreed to an $8 million settlement with the Department of Justice to resolve allegations that its Maryland pharmacies violated the Controlled Substance Act by dispensing controlled substances pursuant to prescriptions that were not issued for a legitimate medical purpose;
- May 13, 2015: CVS agreed to pay $22 million to resolve allegations by the Department of Justice that several retail stores distributed controlled substances based on prescriptions that had not been issued for legitimate medical purposes by a health care provider acting in the usual course of professional practice;
- September 26, 2014: CVS paid the United States $6 million to resolve False Claims Act allegations by the Department of Justice that it knowingly failed to reimburse Medicaid for prescription drug costs paid on behalf of Medicaid beneficiaries.

For a comprehensive listing of CVS violations, *see* https://violationtracker.goodjobsfirst.org/prog.php?parent=cvs-health&order=pen_year&sort=asc&page=1.

[19] Competitive Impact Statement at 17 (quoting *United States v. SBC Commc'ns, Inc.*, 489 F. Supp. 2d 1, 15 (D.D.C. 2007)).

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million covered lives to lessen competition in the health care provider, PBM and pharmacy markets, and raise costs of health care access to competitors and consumers. The Division should revise the Complaint and Proposed Final Judgment to address these anticompetitive effects.

Sincerely,

Laura Boudreau
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