From:	[redacted]
To:	Mucchetti, Peter
Subject:	Proposed Acquisition of Aetna Inc. by CVS Health Corp. - Impact on 340B Safety Net Providers and Their Patients
Date:	Monday, December 17, 2018 9:08:38 PM
Attachments:	CVS Aetna Letter 12 2018.pdf

Please find the attached correspondence from Thomas J. Siepka, R.Ph, MS FACHE. Feel free to contact me with any questions.

Jared M. Barnes, JD, CHC
Assistant Legal Counsel
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[redacted]

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December 17, 2018

BY EMAIL - Peter.J.Mucchetti@usDOJ.gov

Peter Mucchetti
Chief, Healthcare and Consumer Products Section
Antitrust Division
Department of Justice
450 Fifth Street NW, Suite 4100
Washington, DC 20530
P: 202-307-0001

Re: Proposed Acquisition of Aetna Inc. by CVS Health Corp.— Impact on 340B Safety Net Providers and Their Patients

Dear Mr. Mucchetti:

I am writing in my capacity as the Chief Pharmacy Officer at Beth Israel Deaconess Medical Center (BIDMC), and based on my 30 years of experience working for non-profit institutions in the New England Region, I am very concerned about the proposed acquisition of Aetna Inc. by CVS Health Corporation (CVS) under the terms of the proposed Final Judgment filed with the U.S. District Court in *United States of America v. CVS Health Corporation and Aetna, Inc.*, Civ. Action No. 1:18-cv-02340.[1] I and a number of my colleagues throughout the non-profit hospital sector believe that the acquisition would embolden CVS to continue and expand current practices that are detrimental to our non-profit academic medical center and our mission, and particularly damaging to safety net healthcare providers that participate in the federal 340B drug discount program, as well as the patients we are privileged to serve. Actions by CVS Health in states like Ohio have limited competition and driven choice away from patients often into a higher cost model to the direct benefit of CVS Health. Continued vertical integration in this market with an acquisition of an insurer like Aetna will expand this capability and practice of price payment manipulation to pharmacies outside of their CVS pharmacies. A requirement that Aetna divest its individual drug plan business will not protect institutions and their patients from these anti-competitive practices, and patient choice is likely to suffer if this proposed transaction moves forward.

BIDMC is a large, non-profit academic medical center located in Boston, and our larger health system network includes eight community hospital clinical affiliates, dozens of physician practices in neighborhoods across Massachusetts, and six community health center affiliates. These community health centers serve on the front lines of caring for vulnerable patients who would otherwise lack access to local primary care, mental health, substance use, and dental care.

BIDMC maintains a deep commitment to providing high quality medical and behavioral health care to all patients, regardless of insurance status or ability to pay; training the next generation of

[1] 83 Fed. Reg. 52,558 (Oct. 17, 2018).

physicians, nurses and allied health professionals; identifying and implementing new treatments and cures; and maintaining a commitment to the health of our surrounding community. The charitable founding institutions of BIDMC were created more than 120 years ago to serve underserved populations in the greater Boston community. Today, we remain true to that founding mission with unparalleled infrastructure to care for highly diverse and vulnerable populations, including more than 100 staff interpreters and a diverse clinical staff. We are a major Level 1 trauma center and a world-renowned medical research and teaching institution, with more than 11,000 employees.

BIDMC has participated in the 340B drug program since 2009. The federal 340B program requires drug manufacturers to provide discounts on the sale of outpatient drugs to qualified safety net providers, and was created to help safety net providers fulfill their mission of serving uninsured, underinsured, and underserved patient populations. Safety net providers rely on the savings generated from the program to help finance their mission of serving low-income patients. Only providers that are committed to serving low-income and vulnerable patient populations may participate in the 340B program.

As recognized in the federal register notice, CVS "operates the nation's largest retail pharmacy chain; owns a large pharmacy benefit manager called Caremark; and is the nation's second-largest provider of individual prescription drug plans, with over 4.8 million members."[2] CVS operates over 9,800 stores in 49 states, the District of Columbia, and elsewhere.[3]

The Health Resources and Services Administration (HRSA), which administers the 340B program, has permitted safety net providers to provide 340B drugs through both on-site pharmacies operated by the 340B covered entity, as well as through outside pharmacies that contract with the 340B safety net providers to provide 340B drugs to eligible patients. Indeed, thousands of off-site pharmacies, including CVS pharmacies have entered into contract pharmacy arrangements with 340B safety net providers. According to the 340B program database, CVS is second to only one other pharmacy chain in the total number of contract pharmacy arrangements. Under HRSA's original contract pharmacy guidance in 1996,[4] as well as its expanded guidance in 2010,[5] HRSA made clear that contract pharmacy arrangements are a matter of agency law designed to further Congress's intent to benefit 340B safety net providers, ***not for the benefit of for-profit commercial pharmacies***.

CVS, through CVS Caremark, recently announced to several safety net providers that it intended to unilaterally usurp certain 340B savings that safety net providers achieve for its own gain. Specifically, CVS sent letters to safety-net owned pharmacies stating that it was lowering reimbursement rates to the pharmacies because they are owned by a 340B safety net provider. CVS further threatened to drop these pharmacies from the Caremark network if they did not accept the reduced rates, which would severely impede access to needed drugs for low-income patients. There has been no indication, communications or discussions by CVS regarding

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[2] *Id.* at 52,559.
[3] CVS Health, *CVS Health At a Glance*, https://cvshealth.com/about/facts-and-company-information (last visited Dec. 13, 2018).
[4] 61 Fed. Reg. 43,549, 43,552, 43,555 (Aug. 23, 1996).
[5] 75 Fed. Reg. 10,272 (Mar. 5, 2010).

whether these changes in payments would be passed on directly to affected patients. On the other hand, 340B organizations pass these benefits on to patients by expanding access to programs and assistance that are not offered by commercial entities like CVS Health. Taking this benefit away from 340B programs begins to put our programs at risk in servicing the neediest patients in our community. I am very concerned about this discriminatory reimbursement decrease and CVS' move to take 340B savings for its own gain, in direct violation of Congressional intent regarding the 340B program.

This move not only runs contrary to the 340B program's intent, but also clearly represents an anticompetitive move that exploits CVS's near-absolute control over its reimbursement rates and membership network. Significantly, all indications are that CVS sent this letter only to pharmacies that are owned by a 340B safety net provider, and not to commercial pharmacies. There is no explanation as to why the ownership status of the pharmacy would justify such a distinction and this action by CVS is clearly discriminatory and anti-competitive.

The legislative history of the 340B statute states that the purpose of the program is to enable qualified non-profit providers of care to disproportionate numbers of vulnerable patients to stretch their scarce resources so that they may "reach more patients" and furnish "more comprehensive services."[6] Nothing in the 340B statute or its legislative history suggests that the program was intended to benefit for-profit private insurers, pharmacy benefit managers, or their vertically-owned private pharmacies.

Passing the benefit of 340B discounts to these for-profit entities through reduced reimbursement rates thwarts the purpose of the program, and I am confident that HRSA shares our concerns about this threat to the 340B program and its eligible providers. According to HRSA, the 340B program provides additional financial resources to safety net providers without increasing the federal budget by lowering drug acquisition costs while maintaining the providers' revenue from health insurance reimbursements.[7] The difference between a 340B drug's lower acquisition cost and standard non-340B reimbursement represents the very benefit that Congress intended to give to safety net providers when it established the 340B program. HRSA explains that if "covered entities were not able to access resources freed up by the drug discounts when they . . . bill private health insurance, their programs would receive no assistance from the enactment of section 340B and there would be no incentive for them to become covered entities."[8]

A significant loss of 340B savings might force critical safety net providers to dramatically reduce the valuable services they provide to their low-income patients, such as

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[6] H.R. Rep. 102-384, pt.2, at 12 (1992).
[7] Health Res. and Servs. Admin., Hemophilia Treatment Center Manual for Participating in the Drug Pricing Program Established by Section 340B of the Public Health Service Act (2005), http://www.hrsa.gov/hemophiliatreatment/340Bmanual.htm.
[8] *Id.*

deeply discounted prescriptions and medication therapy management.[9] Moreover, while lower 340B reimbursement to 340B provider-owned pharmacies might result in lower costs for health plans and their enrollees, there is no guarantee that such plans would not simply pocket the savings, leaving no benefit to consumers. Furthermore, in this case, CVS's conduct benefits its for-profit commercial pharmacies at the expense of competitor pharmacies owned by340B safety net providers, which is both without any procompetitive justification and contrary to the intention of the 340B program.

I believe the unprecedented market dominance of a combined CVS-Aetna would allow the new company to force 340B safety net providers to accept still more reduced reimbursement rates. Faced with losing a substantial amount of their ability to serve patients who benefit from the 340B program, 340B provider-owned pharmacies would have no choice but to accept whatever reimbursement terms are offered by the company, depriving these safety net providers of the savings they need to fulfill their safety-net mission. As one Department of Justice official observed regarding the alleged cost efficiencies that would result from health insurance mergers, "consumers do not benefit when sellers … merge simply to gain bargaining leverage."[10]

For the above reasons, I oppose the proposed acquisition of Aetna by CVS. If you have any questions or need additional information, please do not hesitate to contact me. Thank you for the opportunity to comment on this important matter.

Sincerely,

Thomas J. Siepka, R.Ph., MS FACHE
VP, Chief Pharmacy Officer
Beth Israel Deaconess Medical Center
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[9] *See* Safety Net Hospitals for Pharmaceutical Access, Demonstrating the Value of the 340B Program to Safety Net Hospitals and the Vulnerable Patients They Serve (June 29, 2011), http://www.340bhealth.org/images/uploads/340B_Value_Report_06-29-11.pdf.

[10] Speech by Assistant Attorney General Bill Baer, Remarks as Prepared for the Delivery at the New Health Care Industry Conference: Integration, Consolidation, Competition in the Wake of the Affordable Care Act at Yale University (Nov.13, 2015).