PARTNERSHIP TO ADVANCE
Cardiovascular
Health

May 23, 2022

Lina M. Khan, Chair
Federal Trade Commission
600 Pennsylvania Avenue, NW
Washington, DC 20580

RE: Solicitation for Public Comments on the Business Practices of Pharmacy Benefit Managers and Their Impact on Independent Pharmacies and Consumers

Dear Chair Khan:

The Partnership to Advance Cardiovascular Health (PACH) is a 501(c)(4) nonprofit advocacy coalition of stakeholder groups that represent patients, patient advocates, health care providers and medical researchers in the cardiovascular space. On behalf of its members, PACH advocates for patient access to FDA-approved therapies and promotes innovation in cardiovascular health care for the millions of Americans who are at high risk for heart disease. Additionally, PACH remains dedicated to the importance of the physician/patient relationship and believes that ultimately a patient's physician is making the decision for the course of care – including prescription drugs – that is in the best health outcome interest of each individual patient.

Given PACH's commitment to heart health, our organization's members are grateful to have the opportunity to share their experience of the impact that Pharmacy Benefit Managers (PBMs) decisions affect access to effective treatments for cardiovascular care. America's progress in decreasing the rates of death from heart disease and stroke has stalled, as reported by the *Wall Street Journal*. The death rate for cardiovascular disease, including heart disease and strokes, has fallen just 4% since 2011. That's after dropping more than 70% over the six decades prior. Particularly alarming is that certain age and demographic groups are actually seeing increases in the rate of cardiovascular related death. Cardiovascular disease accounts for approximately one in three deaths in America each year.

Given the impact on access to care and cardiovascular disease outcomes, we have significant concerns regarding large, vertically integrated Pharmacy Benefit Managers (PBMs) and how their decisions are affecting drug affordability, prescription access and ultimately patient outcomes. PACH applauds the Federal Trade Commission for its leadership in examining PBMs and their impact on independent pharmacies and consumers.

We are largely concerned about PBM implemented steering methods that go against the physician/patient relationship and firmly believe that the course of care should be decided by

the physician who makes the decision based upon the best treatment for each individual patient. Patient steering is a practice employed by pharmacy benefit managers (PBMs) or health plan/insurer owned pharmacies that channels prescriptions to their own wholly owned retail, mail order or specialty pharmacies. The FTC should be made aware of this harmful practice.

Additionally, the PBM practice of non-medical switching is dangerous for patients and can cause many health issues and adverse reactions as we have seen with recent decisions to switch patients who were stable on anticoagulants.

Non-Medical Switching/Formulary Exclusions

For example, effective January 1, 2022, CVS Caremark abruptly dropped all but one direct-acting oral anticoagulant from its commercial pharmacy benefit plan. More than a dozen patient and physician advocacy organizations raised issue with CVS Caremark's change. In one letter to the company, the move was characterized as "dangerously disruptive" to patients. Hundreds of physicians signed on to a similar letter that expressed outrage at the policy change.

In this case, more than two million Americans take blood thinners every day to help prevent – or recover from – life-threatening conditions like stroke, pulmonary embolism, AFib, heart valve replacement and thrombosis. Sudden and disruptive formulary changes can discourage adherence for patients, which can have dire consequences. Patients who abandon anticoagulant therapy have a risk of ischemic stroke that is 2-3 times higher than those who continue therapy. Forcing patients to change medication is risky. Per a 2019 study by the Alliance for Patient Access, nearly one in 10 patients require hospitalization following a non-medical switch.

Among patients' post-switch challenges captured by that research include:

- 39% of patients reported the switch so frustrating that they stopped taking their medication.
- 59% of patients suffered complications with a new medication after a switch, including in many cases, re-emergence of symptoms the previous medication had controlled.
- 40% of patients needed to go back to their health care provider more often following a switch.

Non-medical switching, such as the change that CVS Caremark is instituting, occurs when a managed care plan changes its formulary or cost-sharing requirements in a way that forces stable patients off their prescribed medication. Non-medical switching is problematic for both patients and providers because it actively discourages adherence to therapy and increases the paperwork burden for clinicians and their staff.

Additional visits to treat patients who were otherwise stable add an undue burden to health care providers at a time when burnout is a mounting concern. While non-medical switching

saves the middlemen money, patients are plagued by side effects and inconvenience. And yet, so far, CVS Caremark refuses to grandfather in patients already stable on their existing medication – treatments that were covered just weeks ago. We need to enact commonsense safeguards on non-medical switching. Doing so would be in heart patients' best interest.

Restrictive Formularies/Utilization Management Tools

We increasingly hear from patients and providers that access to therapies is systemically denied, switched or are otherwise out of reach for the most vulnerable heart patients. One of the most egregious examples where market access has been systemically restricted for consumers is the PCSK9 inhibitor (PCSK9i) drug class, and it provides a strong example for what cardiovascular patients increasingly face today across cardiovascular medication classes, devices and even diagnostic testing.

PCSK9 inhibitors are medications that have come to market in the last five years that have proven to significantly reduce the rates of heart attack, stroke and even death. These therapies are appropriate for patients with high lipids that have not responded to traditional statin therapy and are particularly effective for those who have familial hypercholesterolemia (FH), among other patient groups.

PACH has heard from patients and providers across the country that access to these therapies has been restricted at an unprecedented level. In recent years, the Institute for Patient Access found that of patients with commercial insurance plans, nearly 60% of those prescribed a PCSK9 inhibitor were denied access. In some states, nearly every claim was denied. This data is publicly available on our website. PCSK9i access challenges are partly caused by onerous prior authorization requirements.

Market Share

Additionally, we encourage the FTC to examine concerns related to PBMs' market share – which ultimately impacts patient choice, control over prices, access to care and steering towards drugs that make the PBMs more money vs. the most appropriate and efficacious drugs. Three PBMs (CVS Caremark, OptumRx and Express Scripts) now control approximately 75% of the U.S. market – which should be of great concern to the FTC. With 75% market share – these three PBMs push patients to one-size-fits-all care when individual patients need individualized care, especially regarding holistic care and taking into consideration comorbidities. Patients' physicians are in the best position to prescribe individualized treatment for their patients versus a top down one-size-fits-all approach from PBMs.

According to Drug Channels Institute, PBMs' actions also affect consumers by controlling more than 80% of prescription drug formularies – thereby influencing access to drugs, including what drugs insurance companies will cover. Originally, PBMs came into existence to help drive savings for consumers. Instead, they now drive profits for themselves – including schemes that drive up costs for consumers. PBMs lack accountability and transparency in the market.

Conclusion

It's essential to know that many cardiovascular patients have other comorbidities with other medications that need to be carefully managed by their physicians. Non-medical switching by PBMs can lead to adverse health outcomes that could have easily been avoided. PACH believes that patients should receive the medication they are prescribed when it is prescribed to them and that PBMs role in harming patients' access to care along with their intrusion into the physician/patient relationship should be thoroughly examined and addressed by the FTC.

Many medications, devices and even diagnostic tests in the cardiovascular space are facing unprecedented utilization management barriers, and studies now show that these access restrictions contribute to increased cardiovascular events. In your critical regulatory role, we write today to offer our organization as a resource to your office.

Thank you for your consideration, and we look forward to continued dialogue at rgough@advancecardiohealth.org or at (202) 964-2644.

Sincerely,

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