Comments delivered electronically at https://www.regulations.gov/commenton/FTC-2022-0015-0001

May 11, 2022

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

RE: Solicitation for Public Comments on the Impact of Prescription Benefit Managers' Business Practices [FTC-2022-0015]

Dear Ms. Khan,

The American College of Gastroenterology (ACG), the American Gastroenterological Association (AGA), the American Society for Gastrointestinal Endoscopy (ASGE) and the North American Society for Pediatric Gastroenterology, Hepatology and Nutrition (NASPGHAN) appreciate the opportunity to respond to the Federal Trade Commission's (FTC) request for public comment about the practices of Pharmacy Benefit Managers (PBMs) and their impact on patients, physicians, employers, independent and chain pharmacies, and other businesses across the pharmaceutical distribution system.

PBMs set retail prices for pharmaceutical products, negotiate "rebates" from manufacturers based on total sales volume of products, and achieve several types of post-sale price concessions and payments from pharmacies. All of these activities describe a complex flow of funds that has not been transparent to clinicians or to patients.[1] Studies have followed the significant increase in annual rebate payments from drug manufacturers to PBMs relative to revenues, further highlighting the need for policymakers to review market competition and impact on patients' drug costs.[2]

PBMs, insurance companies, and drug manufacturers have created an elaborate and opaque system to control and manipulate drug prices. Meanwhile, physicians are caught in the middle of trying to make treatment decisions that are in the best interest of their patients and navigating insurance company

---

[1] Schulman, K, Dobora, M. The relationship between pharmacy benefit managers (PBMs) and the cost of therapies in the US pharmaceutical market: A policy primer for clinicians. Am Heart J. 2018 Dec;206:113-122.

[2] Weinstein, E, Schulman, K. Exploring payments in the US pharmaceutical market from 2011 to 2019: Update on pharmacy benefit manager impact. Am Heart J. 2020 Sep;227:107-110.

tactics that restrict and delay access to care. “Step therapy” is probably the most likely tactic to be encountered by our physician members and their patients, and can inhibit the continuation or initiation of timely, effective, and sometimes life-saving treatment.

According to an analysis conducted by the Medicare Payment Advisory Commission (MedPAC), rebates totaled $43 billion in 2020, up from $8.5 billion in 2010.[3] Nearly 80 percent of rebates were for drugs with prices under $700.[4] During the same 10-year period, prices, net of rebate, of brand-name drugs nearly doubled in Part D.[5] In January 2021, 832 drugs increased in list price by an average of 4.6 percent —a record number of increases, according to GoodRx Health.[6]

Drug manufacturers typically negotiate rebates on their list prices. But, according to GoodRx, list price increases do end up affecting consumers, especially those with high deductible health plans or without insurance altogether.[7] According to GoodRx research, since 2014, 89 percent and 47 percent of list price increases trickled down to National Average Drug Acquisition Cost (NADAC) and cash price increases one month later that were as high or higher in magnitude, respectively. The NADAC and cash prices are what retail pharmacies and consumers pay for prescription medications, respectively.[8] Conversely, higher list prices may also allow drug manufacturers to offer higher rebates to the PBM or health plan, which may help to lower beneficiary premiums.

Current prescription drug plan design has led to an elaborate maze of pricing, rebates, fees, formularies and patient assistant programs. This has given rise to a tremendous administrative burden on physicians and other health care professionals, who are burdened with prior authorization, step therapy, and non-medical switching – an egregious practice that may force a patient who is stable on current therapy to switch to another pharmacologic treatment that may or may not be as effective.

All stakeholders in the U.S. pharmaceutical system would benefit from diminishing the utilization of these management tools. One study estimates that payers, manufacturers, physicians, and patients together incur approximately $93.3 billion in costs annually on implementing, contesting, and navigating drug utilization management programs. Payers spend approximately $6.0 billion annually administering drug utilization management, and manufacturers spend approximately $24.8 billion supporting patient access in response. Physicians devote approximately $26.7 billion in time spent navigating utilization management, whereas patients spend approximately $35.8 billion annually in drug

---

[3] “Initial findings from MedPAC’s analysis of Part D data on drug rebates and discounts”, Medicare Payment Advisory Commission. April 7, 2022 https://www.medpac.gov/wp-content/uploads/2021/10/MedPAC-DIR-data-slides-April-2022.pdf

[4] ibid.

[5] ibid

[6] 800+ Drugs Became More Expensive This January — The Largest Number of Increases in Years; Feb. 2, 2021 https://www.goodrx.com/healthcare-access/drug-cost-and-savings/january-2021-drug-increases-recap

[7] 800+ Drugs Became More Expensive This January — The Largest Number of Increases in Years; Feb. 2, 2021 https://www.goodrx.com/healthcare-access/drug-cost-and-savings/january-2021-drug-increases-recap

[8] Li D, Marsh T, Meijgaard J, Nguyen A. List Price Increases for Medications Lead to Higher Costs for Consumers. December 2020. GoodRx Research. https://assets.ctfassets.net/4f3rgqwzdznj/1qV2ksMxCCVADxkr46KX2O/dbd9d40eea6cbf0947b6f7e662c62571/List_price_increase_report_goodrx_december_2020.pdf

cost sharing, even after taking advantage of manufacturer and other sources of financial support.[9] The practice of non-medical switching is pervasive among plans managing the use of biological products. Switching most often occurs when a PBM or insurer drops a drug from its formulary and replaces it with an "equivalent" drug.

Gastroenterologists treat disorders of the gastrointestinal tract, such as inflammatory bowel disease (IBD) (specifically Crohn's and colitis), for which biologics are the primary treatment. Brand-name biologics are routinely replaced on formularies by biosimilars with no or limited exceptions to patients who are stable on a medication previously approved, and even though there is strikingly very little to no data on the use of biosimilars in pediatric patient populations. We are also troubled by insufficient communications to providers and patients when these changes are made and resistance by payers and PBMs to allowing exceptions for patients who are stable on their current treatment.

There is no transparency about how these formulary decisions are being made, including whether rebate practices play a role. We encourage the FTC to address anti-competitive conduct by drug manufacturers, PBMs and insurers, including rebates that drug manufacturers provide to payers or PBMs in exchange for market-share guarantees or preferred formulary placement. This practice — also referred to as rebate walls or predatory rebates — may result in giving a higher cost drug preferred formulary placement over a generic or a lower-cost drug. When this happens, patients pay more.

Another trend among payers and PBM companies is to restrict the types of bowel preparation that physicians can prescribe for their patients prior to a colonoscopy. On April 1, 2021, one of the country's largest PBMs announced it would no longer provide coverage of low-volume colonoscopy preparations unless a patient has unsuccessfully tried another bowel preparation. For patients with underlying medical conditions, having a low-volume preparation alternative is critically important. The PBM in question ultimately added what it considers a low-volume prep to its national formulary, despite disagreement by our societies with the PBM over what constitutes a low-volume preparation. This decision is not inconsequential. Lack of access to low-volume preparations may also serve as a deterrent to screening, as patients often cite bowel preparation as a reason for not getting a colonoscopy. Failure of a patient to finish a high-volume preparation can also lead to poor bowel preparation and, therefore, missing the opportunity to identify and remove neoplastic lesions, which could be cancerous.

Rebates and drug prices influence formulary decisions that may not always be in the best interests of patients. At MedPAC's April 7, 2022 meeting, commissioners cautioned against the false dichotomy of allowing rebates or prohibiting them entirely. While anticompetitive behaviors should be scrutinized, we caution against regulatory actions that could lead to higher drug list prices and higher consumer insurance premiums. Our societies encourage policymakers and regulators to pursue a comprehensive approach to ensuring prescription drug access and affordability. We acknowledge the complexity of the issue and appreciate the opportunity on behalf of our patients to share our thoughts on the matter.

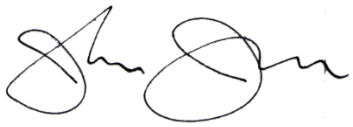
---

[9] Howell, S, Yin, P, Robinson, J. Quantifying The Economic Burden Of Drug Utilization Management On Payers, Manufacturers, Physicians, And Patients. Health Affairs. August 2021. https://pubmed.ncbi.nlm.nih.gov/34339243/

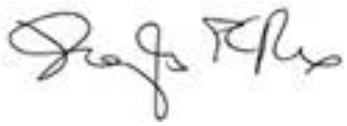
Requests for additional information should be directed to Brad Conway (ACG) at BConway@gi.org, Leslie Narramore (AGA) at lnarramore@gastro.org, Lakitia Mayo (ASGE) at lmayo@asge.org and Camille Bonta (NASPGHAN) at cbonta@summithealthconsulting.com.

Sincerely,

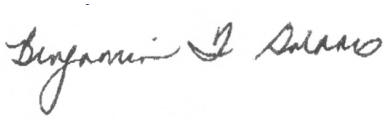
Samir A. Shah, MD, FACG
President, American College of Gastroenterology



John M. Inadomi, MD, AGAF
President, American Gastroenterological Association



Douglas K. Rex, MD, MASGE
President, American Society for Gastrointestinal Endoscopy



Benjamin D. Gold, MD, FAAP, FACG
President, North American Society for Pediatric Gastroenterology, Hepatology and Nutrition