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Dear Chair Khan and Assistant Attorney General Kanter:

Thank you for the opportunity to offer comment on the U.S. Department of Justice and the Federal Trade Commission (“Joint Agencies”) draft Merger Guidelines. American Pharmacy Cooperative, Inc. (“APCI”), consisting of approximately 1,700 community pharmacies across thirty states, believes that the work the Joint Agencies are doing in connection with updating their guidelines is a crucial step in helping to identify and stop potentially illegal mergers.

APCI commends the Joint Agencies in working to develop new guidelines that better account for market realities. The Joint Agencies’ draft Merger Guidelines represent a more sophisticated understanding of the potential threats of horizontal and vertical integration and will no doubt aid in identifying and preventing anti-competitive mergers in the years to come. APCI is particularly pleased to see the evolution of the Joint Agencies’ views on vertical integration and that they are no longer seemingly placing deference on presumptions of increased efficiencies arising out of vertical integration.

Vertical integration in the PBM/insurer space has lessened competition by creating firms that control products/services of their rivals, involved access to rivals competitively sensitive information, and several of the vertical mergers have created market structures that have foreclosed competition. In that regard, the draft Merger Guidelines are a positive development and APCI is encouraged to see they clearly address these threats to competition.

However, and as more fully elaborated below, in order to effectively identify and address anticompetitive mergers in the PBM/insurer space, the Joint Agencies, and their guidelines, should include in their factors and framework an analysis of the past and current practices of the merging parties and whether any of those practices run afoul of Section 5 of the Federal Trade Commission (“FTC”) Act and represent unfair methods of competition. If Section 5 of the FTC Act does not figure centrally into the Joint Agencies factors and frameworks, APCI believes PBMs/insurers will continue to integrate in a way that negatively affects competition

and allows PBMs/insurers to leverage unfair methods of competition that drive up drug prices, reduce access to medications, reduce access to providers, and self-deal.

The FTC updated its policy regarding the scope of unfair methods of competition under Section 5 of the FTC Act in late 2022 and it has the potential to be one of the most effective tools in dealing with PBM/insurer practices that slip into gaps in traditional Clayton Act analysis and other antitrust laws.¹

Community Pharmacy has long called out PBM/insurer practices that negatively impact competition and recent federal reports bear out community pharmacy's warnings.

APCI's members spend their days caring for their patients. Their services include but are not limited to dispensing medications, offering medication counseling, assisting with medication and device selection, collaborating with primary care providers and health systems, administering vaccines, testing for certain disease states, and treating for certain disease states.

Our members are amongst the most accessible providers in the nation and, in many cases, are the only providers in medically underserved areas as well as rural areas.² APCI's members and other community pharmacies stayed open during the COVID-19 pandemic, answering the call and willingly and capably provided testing and vaccine administration pursuant to the PREP Act.³

In light of the central role APCI's members and other community pharmacies play in today's healthcare system, community pharmacy has seen and felt first-hand the harms to competition that have been wrought by vertical integration of PBMs with insurers, and affiliated pharmacies.

The Joint Agencies know well the big three PBMs and their affiliated insurers, as well as their respective market shares.⁴ The Joint Agencies likely also know well the position of community pharmacy with regard to the practices of PBMs and their negative effect on pharmacies and their patients.⁵ The Joint Agencies know these positions because community pharmacy has spoken out against vertical integration of PBMs/insurers and their claims of "lowered costs,"

¹ Federal Trade Commission, Policy Statement Regarding the Scope of Unfair Methods of Competition Under Section 5 of the Federal Trade Commission Act, November 10, 2022, available online at https://www.ftc.gov/system/files/ftc_gov/pdf/Policy%20Statement%20of%20the%20Federal%20Trade%20Commission%20on%20Rebates%20and%20Fees%20in%20Exchange%20for%20Excluding%20Lower-Cost%20Drug%20Products.near%20final.pdf.

² See Lucas A. Bernenbrok et al., "Access to community pharmacies: A nationwide geographic information systems cross-sectional analysis," Journal for American Pharmacists Association, July 12, 2022, available online at [https://www.japha.org/article/S1544-3191\(22\)00233-3/fulltext](https://www.japha.org/article/S1544-3191(22)00233-3/fulltext).

³ See Jake Galdo, "Community Pharmacies Stepped Up During Covid-and Changed for Good," Wired, September 7, 2021, available online at <https://www.wired.com/story/covid-19-prep-act-pharmacies/>.

⁴ See FTC, FTC Launches Inquiry Into Prescription Drug Middlemen Industry [press release], June 7, 2022, available online at <https://www.ftc.gov/news-events/news/press-releases/2022/06/ftc-launches-inquiry-prescription-drug-middlemen-industry>.

⁵ See Darrel Rowland, "Federal Trade Commission rejects pharmacy benefit managers probe pushed by Biden appointee," The Columbus Dispatch, February 17, 2022, available online at <https://www.dispatch.com/story/news/2022/02/17/prescription-drug-costs-ftc-declines-go-after-pbms-despite-pharmacists-testimony/6787109001/>.

and “increased efficiencies,” they maintain come from horizontal and vertical integration. Unfortunately, PBM/insurer claims won the day in years past with the Joint Agencies largely giving the green light on mega mergers involving PBMs and insurers.

However, things have not born out as promised by the PBMs and insurers. In pharmacy today, core vertically integrated PBM/insurer practices include the following:

- Rebates: Rebate practices of large PBMs include (1) denying patients the benefit of drug maker rebates at the point of sale; (2) mandating that patients pay for more expensive brand drugs as a condition of coverage when there are lower cost generic equivalents available, including in the deductible phase; and (3) engaging in rebate driven restrictive/exclusionary formulary practices.⁶
- Drug pricing methodologies: PBMs use a variety of complex methodologies to set the prices patients and payers pay for prescription drugs. PBMs are often able to play arbitrage, exploiting pricing variations between the parties as well as through the use of drug maker rebates and pharmacy discounts.⁷ These practices include the practice of spread pricing (charging plan sponsors more for a drug than a pharmacy is reimbursed), and DIR fees in Medicare Part D whereby patient cost shares and deductibles are based on inflated prices at the counter with the PBMs clawing pharmacy discounts back from pharmacies retroactively thereby denying patients the benefit of the discounts and increasing the prices patients pay at the counter.⁸
- Patient steering: A practice that has grown as a result of vertical integration, PBMs are engaging in tactics to steer patients to PBM/insurer affiliated pharmacies.⁹ Large PBMs aggressively target patients on specialty medications to treat serious conditions such as cancer and HIV, as well as patients on medications to manage chronic conditions such as diabetes, high blood pressure and heart disease.¹⁰

⁶ Xcenda, “Skyrocketing growth in PBM formulary exclusions continues to raise concerns about patient access,” September 16, 2020, available online at https://www.xcenda.com/-/media/assets/xcenda/english/content-assets/white-papers-issue-briefs-studies-pdf/xcenda_pbm_exclusion_may_2022.pdf; see also 46Brooklyn, “Wreck-fidera: How Medicare Part D has hidden the benefits of generic competition for a blockbuster Multiple Sclerosis treatment,” December 1, 2021, available online at: <https://www.46brooklyn.com/research/2021/12/1/tecfidera>.

⁷ Frier Levitt - commissioned by the Community Oncology Alliance, “Pharmacy Benefit Manager Expose: How PBMs Adversely Impact Cancer Care While Profiting at the Expense of Patients, Providers, Employers, and Taxpayers,” February 2022, available online at: https://mycoa.s3.amazonaws.com/1678994901525_COA_FL_PBM_Expose_2-2022.pdf.

⁸ Id.

⁹ Id.; see also Marty Schladen, Catherine Candisky, “Mail-order pharmacy system delays care for some patients,” The Columbus Dispatch, June 3, 2018, available online at <https://www.dispatch.com/story/lifestyle/health-fitness/2018/06/03/mail-order-pharmacy-system-delays/12069189007/>.

¹⁰ Frier Levitt - commissioned by the Community Oncology Alliance, “Pharmacy Benefit Manager Expose: How PBMs Adversely Impact Cancer Care While Profiting at the Expense of Patients, Providers, Employers, and Taxpayers,” February 2022, available online at: https://mycoa.s3.amazonaws.com/1678994901525_COA_FL_PBM_Expose_2-2022.pdf; see also Marty Schladen, “Pharmacist: CVS dominates cancer-drug business,” The Columbus Dispatch, June 3, 2018, available online at <https://www.dispatch.com/story/lifestyle/health-fitness/2018/06/03/pharmacist-cvs-dominates-cancer-drug/12069174007/>.

Importantly, while pharmacy has been sounding the alarm on these practices and their impact on competition, access to care, and patient outcomes, in the past year and a half several studies have been released from various federal agencies that bear out warnings by community pharmacy.

In June of 2022, the Office of Inspector General released a report on the impact of Medicare Part D prescription drug plan brand requirements in connection with Hepatitis C drugs.¹¹ The report found that many plans failed to include lower cost authorized generics of certain Hepatitis C drugs and rather, required more expensive brand name drugs.¹² The report also found increased costs to the Medicare program as a result of brand preferences and, more importantly, found that “because beneficiary cost-sharing is based on pre-rebate prices, the use of higher-cost hepatitis C drugs in Part D led to thousands of dollars in additional costs for some Medicare beneficiaries.”¹³

In July of 2023, a landmark study was released by the Medicare Payment Advisory Commission (“MedPAC”) focusing on Medicare Part D in the year 2021.¹⁴ In connection with the extent of vertical integration with PBMs, insurers, affiliated pharmacies, and Part D plans, the report identified, amongst other things:

- PBMs often paid their vertically integrated pharmacies more than non-affiliated pharmacies;
- Vertical integration created conflicts of interest and that a vertically integrated entity can benefit from higher payments to their vertically integrated pharmacies;
- Vertical integration resulted in higher costs to seniors;
- PBMs denied beneficiaries \$50 billion drug maker rebates at the counter in 2021 alone;
- 8% of the time, PBMs paid less for a drug than the patient paid out of pocket; and
- One PBM charged patients an average cost share for an asthma drug that was 156% more than the PBM was itself paying for the drug.¹⁵

Most recently, in September of 2023, the U.S. Government Accountability Office (“GAO”) released a report analyzing CMS data and found, amongst other things, that for the seventy-nine highest rebated drugs in 2021, beneficiary payments were \$21 million and plan sponsor expenditures after rebates were only \$5.3 billion, a direct results of PBMs and prescription drug plans not passing rebates back to patients at the pharmacy counter¹⁶ Here it is important to remember that often the prescription drug plans are vertically integrated with the PBMs.

¹¹ U.S. Department of Health and Human Services Office of Inspector General, “Part D Plan Preference for Higher Cost Hepatitis C Drugs Led to Higher Medicare Beneficiary Spending,” August 2022, available online at <https://oig.hhs.gov/oei/reports/OEI-BL-21-00200.pdf>.

¹² Id.

¹³ Id.

¹⁴ Medicare Payment Advisory Commission, “Medicare and the Health Care Delivery System,” Chapter 2, June 2022, available online at: https://www.medpac.gov/wp-content/uploads/2022/06/Jun22_MedPAC_Report_to_Congress_v4_SEC.pdf.

¹⁵ Id.

¹⁶ The United States Government Accountability Office, “Medicare Part D: CMS Should Monitor Effects of Rebates on Plan Formularies and Beneficiary Spending,” September 2023, available online at <https://www.gao.gov/assets/gao-23-105270.pdf>.

Of course, the FTC itself has not been inactive on the PBM front, launching a 6B study of practices employed by the six largest PBMs in June of 2022¹⁷, and, that same month, issuing a policy statement on rebates and fees in exchange for excluding lower cost drug products from formularies.¹⁸ In its policy statement on rebates, the FTC cited several authorities that may apply to exclusionary rebate practices including Section 5 of the FTC Act and emphasized that:

[T]HE [FTC] recognizes the life and death stakes of this work and is committed to acting expeditiously.¹⁹

APCI believes the FTC was correct in recognizing the life and death stakes with regard to rebate practices of PBMs as higher drug prices compromise patient compliance with prescription drug regimens and can lead to poorer patient outcomes.²⁰ This is why it is critical that the final Merger Guidelines include the tools necessary to rein in mergers and acquisitions involving PBMs/insurers that have the potential to, amongst other things, increase drug prices. To do so, however, scrutiny of past and current practices of PBMs to determine whether any of their practices constitute unfair methods of competition must be central to the draft Merger Guidelines and to pre-consummation and post consummation merger investigations.

Section 5 of the FTC Act should figure centrally into the factors and frameworks considered by the Joint Agencies in pre-consummation and post-consummation merger investigations of PBMS/insurers.

It is hard to underestimate the importance of the aforementioned studies, the pending 6b study, the FTC's policy statements on rebates, and the draft Merger Guidelines. However, nothing represents a more promising development for ending abusive PBM/insurer practices and mergers that allow PBMs/insurers to leverage those practices than the FTC's policy statement regarding unfair methods of competition.

As more fully elaborated below, if the Joint Agencies are going to be able to stop mergers and acquisitions in the PBM/insurer space that harm competition, Section 5 of the FTC must figure centrally in the factors and frameworks relied upon by the Joint Agencies when investigating mergers. APCI is concerned that rather than scrutiny of unfair methods of competition figuring prominently in the draft Merger Guidelines, Section 5 of the FTC Act received little more than a footnote.

¹⁷ See FTC, FTC Launches Inquiry Into Prescription Drug Middlemen Industry [press release], June 7, 2022, available online at <https://www.ftc.gov/news-events/news/press-releases/2022/06/ftc-launches-inquiry-prescription-drug-middlemen-industry>.

¹⁸ Federal Trade Commission, "Policy Statement of the Federal Trade Commission on Rebates and Fees in Exchange for Excluding Lower-Cost Drug Products, June 2022, available online at https://www.ftc.gov/system/files/ftc_gov/pdf/Policy%20Statement%20of%20the%20Federal%20Trade%20Commission%20on%20Rebates%20and%20Fees%20in%20Exchange%20for%20Excluding%20Lower-Cost%20Drug%20Products.near%20final.pdf.

¹⁹ Id.

²⁰ Eaddy et al. How Patient Cost-Sharing trends Affect Adherence and Outcomes: A literature review PT. 2012 Jan; 37(1):45-55. Available online at <https://pubmed.ncbi.nlm.nih.gov/22346336/>.

Analysis of potential violations of Section 5 of the FTC Act is necessary in order to identify and protect the public from PBMs/insurers relying on vertical integration to leverage unfair methods of competition.

As set forth in the FTC's Policy Statement regarding methods of unfair competition, Section 5 of the FTC Act can prohibit, amongst other things, (1) incipient violations of anti-trust laws of actors who may not have monopoly power or whose conduct has the tendency to ripen into anti-trust violation; and (2) conduct that violates the spirit of antitrust laws but may not be covered by the literal language of anti-trust laws or that may fall into a "gap," in those laws.²¹

Historically, as PBMs have merged with pharmacies or where PBMs have acquired or been acquired by large insurers, traditional analysis has not seemingly focused on the practices of PBMS that may constitute unfair methods of competition and run afoul of Section 5 of the FTC Act. Rather, it appears to APCI that the Joint Agencies have focused more on factors including market share, relevant markets, and market concentration levels utilizing the Herfindahl-Hirschman Index.

While analysis of the foregoing market factors is relevant and important, had Joint Agency analysis scrutinized the practices of large PBMs (including practices pertaining to rebates, steering, and setting drug prices) for potential unfair methods of competition, the Joint Agencies could have likely acted to prevent the vertical integration that PBMs/insurers leveraged to further profiteer off of already problematic practices.

As the aforementioned studies bear out, vertically integrated PBMs/insurers have paid their pharmacies more, forced patients to pay for more expensive brand name drugs when there are cheaper generics available, denied patients the benefits of drug maker discounts to the tune of billions of dollars a year, restricted formularies, charged beneficiaries more for drugs than the PBMs/insurers themselves paid, and raised drug prices.²²

When PBMs/insurers look to integrate with each other and other vertical actors in the healthcare space, it presents the Joint Agencies with the perfect opportunity to scrutinize the foregoing practices to see if they go beyond competition on the merits (coercive, exploitive, collusive, abusive, deceptive, predatory) and to see if they negatively affect competition (harm to consumers, reduction in competition limiting of choice, raising prices, lowering quality) thereby constituting unfair methods of competition in violation of Section 5 of the FTC Act.²³

²¹ Federal Trade Commission, "Policy Statement Regarding the Scope of Unfair Methods of Competition Under Section 5 of the Federal Trade Commission Act Commission." File No. P221202, November 10, 2022, available online at

https://www.ftc.gov/system/files/ftc_gov/pdf/p221202sec5enforcementpolicystatement_002.pdf.

²² See Footnotes 11-16.

²³ See Federal Trade Commission, "Policy Statement Regarding the Scope of Unfair Methods of Competition Under Section 5 of the Federal Trade Commission Act Commission." File No. P221202, November 10, 2022, available online at

https://www.ftc.gov/system/files/ftc_gov/pdf/p221202sec5enforcementpolicystatement_002.pdf.

Analysis under Section 5 of the FTC Act can identify PBM/insurer mergers that leverage problematic rebate practices in a way that traditional merger analysis under the Clayton Act may miss.

The FTC's policy position with regard to rebates and the role they play in exclusionary prescription drug formularies has been made clear.²⁴ Beyond the financial implications of PBM negotiated rebates shifting costs, creating misaligned incentives, and foreclosing competition, the FTC has rightly recognized there are also implications to the health and lives of Americans.²⁵

Despite the FTC's on the record concerns with regard to rebates, certain recent acquisitions by PBMs of prescriber entities that potentially implicate PBM/insurer rebate practices have seemingly gone unchallenged by the Joint Agencies.²⁶ Joint Agency scrutiny likely focused on market share, relevant markets, and market concentrations instead of past and current rebate practices and how the acquisition of prescriber entities may further leverage PBM/insurer rebate practices.

The threat of PBMs/insurers vertically integrating via acquisition into the prescriber market is particularly insidious. It enables PBMs/insurers to expand control from drug prices, rebates, formularies, insurance premiums, and networks, to potentially control what drugs are prescribed or are not prescribed by physicians and other prescribers and where those prescriptions may be sent.

PBMs/insurers already possess a stunning degree control over the availability of prescription drugs including designing exclusionary formularies, requiring step therapy and prior authorizations, withholding coverage for certain drugs, and mandating brand name drugs when cheaper generics are available. The implications to PBMs/insurers also possibly controlling what drugs are or are not prescribed by physicians and other prescribers are chilling.

While traditional methods of merger analysis and the draft Merger Guidelines may fail to identify such a threat, Section 5 of the FTC Act provides the tools necessary to evaluate and stop such potential threats to competitive conditions when they represent unfair methods of competition.

Mergers can constitute unfair methods of competition in violation of Section 5 of the FTC

The FTC's November 2022 Guidelines themselves provide historical examples of violations of the FTC that include:

²⁴ Federal Trade Commission, "Policy Statement of the Federal Trade Commission on Rebates and Fees in Exchange for Excluding Lower-Cost Drug Products, June 2022, available online at https://www.ftc.gov/system/files/ftc_gov/pdf/Policy%20Statement%20of%20the%20Federal%20Trade%20Commission%20on%20Rebates%20and%20Fees%20in%20Exchange%20for%20Excluding%20Lower-Cost%20Drug%20Products.near%20final.pdf.

²⁵ Id.

²⁶ See CVS, "CVS Health completes acquisition of Oak Street Health," May 2, 2023, available online at <https://www.cvshealth.com/news/company-news/cvs-health-completes-acquisition-of-oak-street-health.html>; see also CVS, "CVS Health completes acquisition of Signify Health," March 29, 2023, available online at <https://www.cvshealth.com/news/company-news/cvs-health-completes-acquisition-of-signify-health.html>.

- Mergers, acquisition, or joint ventures that have a tendency to ripen into violations of anti-trust laws; and
- A series of mergers, acquisitions, or joint ventures that tend to bring about the harms that the antitrust laws were designed to prevent, but individually may not have violated the antitrust laws.²⁷

In addition, over the years the Joint Agencies have included violations of Section 5 of the FTC Act as grounds to seek to block mergers.²⁸

Because mergers themselves can violate Section 5 of the FTC Act and because Section 5 is often relied on in complaints filed by the Joint Agencies, analysis of Section 5 of the FTC Act should play a central role in the factors and frameworks the Joint Agencies consider when investigating mergers.

Conclusion

APCI commends the Joint Agencies for their work in connection with the draft Merger Guidelines. The draft Merger Guidelines are a much-needed improvement to the horizontal and vertical guidelines of years past and are well positioned to better identify and stop anticompetitive mergers across industries.

However, APCI is concerned that the draft Merger Guidelines fail to include scrutiny of past and current practices of the merging parties for violations of Section 5 of the FTC Act and how any suspect practices may be leveraged with further integration. If Section 5 of the FTC Act is not a part of the factors and frameworks the Joint Agencies consider when reviewing the legality of PBM/insurer mergers, PBMs/insurers will continue to be able to integrate with other actors in the healthcare space, with their bad practices slipping through the cracks of the Clayton Act and other antitrust laws.

Should you have any questions or APCI can provide anything additional, please contact the undersigned at gregr@apcinet.com. Thank you for the opportunity to comment and for your attention to this important matter.

Sincerely,

S/ Greg Reybold

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²⁷ See Federal Trade Commission, “Policy Statement Regarding the Scope of Unfair Methods of Competition Under Section 5 of the Federal Trade Commission Act Commission.” File No. P221202, November 10, 2022, available online at https://www.ftc.gov/system/files/ftc_gov/pdf/p221202sec5enforcementpolicystatement_002.pdf.

²⁸ Id.