United States Senate
COMMITTEE ON THE JUDICIARY
WASHINGTON, DC 20510–6275

March 09, 2022

The Honorable Lina Khan
Chairwoman
Federal Trade Commission
600 Pennsylvania Avenue, N.W.
Washington, D.C. 20580

Dear Chair Khan,

I write in regards to the Federal Trade Commission's (FTC) recent deadlocked vote on February 17 to initiate a 6(b) Study into the business practices of Pharmacy Benefit Managers (PBMs). I urge you to find consensus and vote to move forward on a revised 6(b) study to examine competitive concerns within the PBM industry.

As you know, PBMs operate with little to no transparency, making it very difficult if not impossible to understand the flow of money in the prescription drug marketplace and how PBMs determine the prices for prescription drugs. Recent consolidations between PBMs and insurance providers have resulted in vertical integration whereby a small number of companies now manage the vast majority of prescription drug benefits. CVS/Caremark, OptumRx and Express Scripts control roughly 75% of the PBM market and are owned by insurers Aetna, United Healthcare, and Cigna, respectively.

I have introduced legislation, S. 1388 the Prescription Pricing for the People Act, which would require the FTC to conduct a study and report to Congress on the effects of consolidation and potentially anticompetitive behavior that may impact prescription drug pricing. A few of the provisions required to be examined in the report include whether PBMs charge certain payers a higher price than competing pharmacies or steer patients to pharmacies at which the PBM has an ownership stake, whether PBMs use formulary designs to depress market share of low cost prescription drugs, and if more information about roles of intermediaries in the healthcare marketplace would benefit consumers. This legislation was approved unanimously by the Judiciary Committee last year.

There is widespread bipartisan support for examining PBMs and looking into whether they are causing Americans to pay higher prices for prescription drugs. I hear stories about rising drug costs all the time at my 99 county meetings. A study into the business practices of these intermediaries would provide transparency and insight about possible competitive harms.

Looking at the record from the FTC's open hearing on February 17, there is widespread support amongst all of the Commissioners to conduct a 6(b) study into the business practices of PBMs. A more targeted focus for the study on the impact of PBMs on consumers and the out of pocket costs of their prescription drugs appears to be an area of agreement. I encourage you to come together with your fellow commissioners to find common ground on a meaningful 6(b) study.

Sincerely,

Chuck Grassley

Charles E. Grassley
Ranking Member
U.S. Senate Committee on the Judiciary

CC:
Commissioner Phillips
Commissioner Slaughter
Commissioner Wilson

UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION
WASHINGTON, D.C. 20580

Office of the Secretary

May 17, 2022

The Honorable Mike Braun
United States Senate
Washington, D.C. 20510

Dear Senator Braun,

Thank you for the May 16, 2022, letter from you and other Senators providing your views regarding the Commission's request for public comments on the impact of pharmacy benefit managers' practices.[1] Your letter will be placed on the docket with other public comments.[2]

We appreciate your interest in this important issue, and I can assure you that the information you have provided will be carefully considered. Please let us know whenever we can be of service with respect to any other matter.

Sincerely,

April J. Tabor
Secretary

[1] FTC Requests Public Comments on the Impact of Pharmacy Benefit Managers' Practices, (February 24, 2022), *available at* https://www.ftc.gov/news-events/news/press-releases/2022/02/ftc-requests-public-comments-impact-pharmacy-benefit-managers-practices.

[2] Solicitation for Public Comments on the Impact of Prescription Benefit Managers' Business Practices, *available at* https://www.regulations.gov/docket/FTC-2022-0015.

UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION
WASHINGTON, D.C. 20580

Office of the Secretary

May 17, 2022

The Honorable Charles E. Grassley
United States Senate
Washington, D.C. 20510

Dear Senator Grassley,

Thank you for the May 16, 2022, letter from you and other Senators providing your views regarding the Commission's request for public comments on the impact of pharmacy benefit managers' practices.[1] Your letter will be placed on the docket with other public comments.[2]

We appreciate your interest in this important issue, and I can assure you that the information you have provided will be carefully considered. Please let us know whenever we can be of service with respect to any other matter.

Sincerely,

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Secretary

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UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION
WASHINGTON, D.C. 20580

Office of the Secretary

May 17, 2022

The Honorable Ron Wyden
United States Senate
Washington, D.C. 20510

Dear Senator Wyden,

Thank you for the May 16, 2022, letter from you and other Senators providing your views regarding the Commission's request for public comments on the impact of pharmacy benefit managers' practices.[1] Your letter will be placed on the docket with other public comments.[2]

We appreciate your interest in this important issue, and I can assure you that the information you have provided will be carefully considered. Please let us know whenever we can be of service with respect to any other matter.

Sincerely,

April J. Tabor
Secretary

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UNITED STATES OF AMERICA
Federal Trade Commission
WASHINGTON, D.C. 20580

Office of the Chair

September 19, 2022

The Honorable James Lankford
United States Senate
Washington, D.C. 20510

Dear Senator Lankford:

Thank you for your June 15, 2022 letter in support of the Federal Trade Commission's use of its investigatory authority under Section 6(b) of the FTC Act to issue orders to pharmacy benefit managers ("PBMs") to study a range of their practices that may affect drug affordability and access.

In June, the FTC announced that it would initiate a 6(b) inquiry into the business practices of PBMs.[1] The inquiry requires the six largest pharmacy benefit managers—CVS Caremark; Express Scripts, Inc.; OptumRx, Inc.; Humana Inc.; Prime Therapeutics LLC; and MedImpact Healthcare Systems, Inc.—to provide information and records regarding their business practices. This inquiry builds on the significant public record developed in response to the request for information about PBMs that the agency launched on February 24, 2022.[2] The agency has received more than 24,000 public comments to date.[3]

The FTC also announced a policy statement that lays out concerns about certain business practices that may be resulting in Americans having to pay higher prices for essential medicines.[4] The policy statement notes that the FTC has a variety of statutory authorities that it can apply to assess whether those practices may be illegal.

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[1] Press Release, Fed. Trade Comm'n, FTC Launches Inquiry Into Prescription Drug Middlemen Industry (June 7, 2022), https://www ftc.gov/news-events/news/press-releases/2022/06/ftc-launches-inquiry-prescription-drug-middlemen-industry.

[2] Press Release, Fed. Trade Comm'n, FTC Requests Public Comments on the Impact of Pharmacy Benefit Managers' Practices (Feb. 24, 2022), https://www ftc.gov/news-events/news/press-releases/2022/02/ftc-requests-public-comments-impact-pharmacy-benefit-managers-practices.

[3] *See* Regulations.gov, Solicitation for Public Comments on the Business Practices of Pharmacy Benefit Managers and Their Impact on Independent Pharmacies and Consumers, FTC-2022-0015 (Feb. 24, 2022), https://www.regulations.gov/docket/FTC-2022-0015.

[4] Press Release, Fed. Trade Comm'n, FTC to Ramp Up Enforcement Against Any Illegal Rebate Schemes, Bribes to Prescription Drug Middleman That Block Cheaper Drugs (Jun. 16, 2022), https://www.ftc.gov/news-events/news/press-releases/2022/06/ftc-ramp-up-enforcement-against-illegal-rebate-schemes; *see also* Fed. Trade Comm'n, Policy Statement of the Federal Trade Commission on Rebates and Fees in Exchange for Excluding Lower Cost Drug Products, FTC File No. P221201 (June 16, 2022), https://www ftc.gov/legal-library/browse/policy-statement-federal-trade-commission-rebates-fees-exchange-excluding-lower-cost-drug-products.

The PBM inquiry will examine several of the most common complaints about PBMs and will seek to assist policymakers in determining whether Americans would benefit from reforms to this critical industry. Our inquiry is aimed at shedding light on several practices that have drawn scrutiny in recent years, including: fees and clawbacks charged to unaffiliated pharmacies; methods to steer patients towards pharmacy benefit manager-owned pharmacies; potentially unfair audits of independent pharmacies; complicated and opaque methods to determine pharmacy reimbursement; the prevalence of prior authorizations and other administrative restrictions; the use of specialty drug lists and surrounding specialty drug policies; and the impact of rebates and fees from drug manufacturers on formulary design and the costs of prescription drugs to payers and patients.

I view this inquiry as a critical step in more closely scrutinizing business practices across the pharmaceutical supply chain that can raise drug prices and limit access for patients and that may contribute to the shuttering of independent pharmacies across the country. Given that PBMs' practices can have life-and-death consequences for Americans, the FTC has a moral imperative to act with urgency in that realm. If we find evidence of any illegal practices—be it unfair methods of competition or unfair or deceptive practices—I will strive to ensure that the FTC vigorously brings our full authorities to bear in response.

Thank you again for raising this topic and your vigilance in promoting fair competition in the drug industry. If you or your staff have any questions, please contact Jeanne Bumpus, the Director of the FTC's Office of Congressional Relations, at (202) 326-2195.

Sincerely,

Lina Khan

Lina M. Khan
Chair, Federal Trade Commission

UNITED STATES OF AMERICA
Federal Trade Commission
WASHINGTON, D.C. 20580

Office of the Chair

November 8, 2022

The Honorable Marsha Blackburn
United States Senate
Washington, D.C. 20510

Dear Senator Blackburn:

Thank you for your October 6, 2022 letter supporting the Federal Trade Commission's recently launched study of certain pharmacy benefit manager ("PBM") industry practices and requesting the timely completion of that study as well as the timely issuance of a report of the study's findings.

I view this inquiry as a critical step in more closely scrutinizing business practices across the pharmaceutical supply chain that can raise drug prices, limit access for patients, and contribute to the shuttering of independent pharmacies across the country. If we find evidence of any illegal practices—be it unfair methods of competition or unfair or deceptive practices—I will strive to ensure that the FTC vigorously brings our full authorities to bear in response.

Given that PBMs' practices can have life-and-death consequences for Americans, we are striving to complete the study and issue a report on it as soon as possible. But we are also considering other tools, such as law enforcement, to combat any unlawful PBM practices. In June 2022, we issued a policy statement that lays out concerns about certain business practices that may be resulting in Americans having to pay higher prices for essential medicines, including insulin.[1] The policy statement notes that the FTC has a variety of statutory authorities that it can apply to assess whether those practices may be illegal.

I also want to take this opportunity to ask for your support for two measures essential for a vigorous FTC that can fully protect Americans from unlawful business practices: (1) restoring the Commission's full authority to return money to victimized consumers;[2] and (2) providing the Commission with the funding necessary for us to fulfill our vital mission. The Commission's

[1] Press Release, Fed. Trade Comm'n, FTC to Ramp Up Enforcement Against Any Illegal Rebate Schemes, Bribes to Prescription Drug Middleman That Block Cheaper Drugs (Jun. 16, 2022), https://www.ftc.gov/news-events/news/press-releases/2022/06/ftc-ramp-up-enforcement-against-illegal-rebate-schemes; *see also* Fed. Trade Comm'n, Policy Statement of the Federal Trade Commission on Rebates and Fees in Exchange for Excluding Lower Cost Drug Products, FTC File No. P221201 (June 16, 2022), https://www.ftc.gov/legal-library/browse/policy-statement-federal-trade-commission-rebates-fees-exchange-excluding-lower-cost-drug-products.

[2] In April 2021 the Supreme Court held that Section 13(b) of the FTC Act does not authorize federal courts to require defendants to pay refunds to harmed consumers or give up the unjust gains they earned from breaking the law. *AMG Capital Mgmt., LLC. v. FTC*, 141 S. Ct. 1341 (2021).

loss of its ability to obtain monetary relief under 13(b) of the FTC Act has already had a profound effect on consumers and honest businesses: by conservative estimates, this court decision has caused consumers to already lose out on more than $1.5 billion of relief that the agency previously could have obtained under Section 13(b), and the losses increase with each passing day.[3]

As for funding, despite having a broad mandate from Congress and being on the front lines of many of the most pressing issues Americans face today, the agency's funding has not kept up with the additional demands on its resources. Indeed, the number of full-time employees at the FTC is about two-thirds of what it was at the beginning of 1980, even as the nation's GDP has increased six-fold. Demands on the Commission continue to grow as we receive more consumer complaints, review more corporate mergers, conduct more complex and expensive litigation, and respond to burgeoning requests for research and investigation of various economic sectors. While we constantly strive to enforce the law to the best of our capabilities, there is no doubt that despite the increased appropriations Congress has provided in recent years, we continue to lack sufficient funding. I look forward to working with Congress to ensure that the Commission has the resources and tools it needs to vigorously protect Americans from unlawful business practices throughout the economy.

Thank you again for raising this topic and your vigilance in promoting fair competition in the drug industry. If you or your staff have any questions, please contact Jeanne Bumpus, the Director of the FTC's Office of Congressional Relations, at (202) 326-2195.

Sincerely,

Lina Khan

Lina M. Khan
Chair, Federal Trade Commission

[3] Statement of Commissioner Rebecca Kelly Slaughter Joined by Chair Lina M. Khan Regarding Section 13(b) of the FTC Act (Apr. 28, 2022), https://www.ftc.gov/system/files/ftc_gov/pdf/Statement%20of%20Comm%27r%20Slaughter%20Joined%20by%20Chair%20Khan%20Regarding%20Section%2013%28b%29%20of%20the%20FTC%20Act_April%202022.pdf.

UNITED STATES OF AMERICA
Federal Trade Commission
WASHINGTON, D.C. 20580

Office of the Chair

November 8, 2022

The Honorable Maria Cantwell
United States Senate
Washington, D.C. 20510

Dear Senator Cantwell:

Thank you for your October 6, 2022 letter supporting the Federal Trade Commission's recently launched study of certain pharmacy benefit manager ("PBM") industry practices and requesting the timely completion of that study as well as the timely issuance of a report of the study's findings.

I view this inquiry as a critical step in more closely scrutinizing business practices across the pharmaceutical supply chain that can raise drug prices, limit access for patients, and contribute to the shuttering of independent pharmacies across the country. If we find evidence of any illegal practices—be it unfair methods of competition or unfair or deceptive practices—I will strive to ensure that the FTC vigorously brings our full authorities to bear in response.

Given that PBMs' practices can have life-and-death consequences for Americans, we are striving to complete the study and issue a report on it as soon as possible. But we are also considering other tools, such as law enforcement, to combat any unlawful PBM practices. In June 2022, we issued a policy statement that lays out concerns about certain business practices that may be resulting in Americans having to pay higher prices for essential medicines, including insulin.[1] The policy statement notes that the FTC has a variety of statutory authorities that it can apply to assess whether those practices may be illegal.

Finally, the Commission's ability to fully deliver on its mission requires that we be equipped with both strong legal authorities and adequate resources, and I am grateful for your support on both fronts.[2] As you know, the number of full-time employees at the FTC is about

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[1] Press Release, Fed. Trade Comm'n, FTC to Ramp Up Enforcement Against Any Illegal Rebate Schemes, Bribes to Prescription Drug Middleman That Block Cheaper Drugs (Jun. 16, 2022), https://www.ftc.gov/news-events/news/press-releases/2022/06/ftc-ramp-up-enforcement-against-illegal-rebate-schemes; *see also* Fed. Trade Comm'n, Policy Statement of the Federal Trade Commission on Rebates and Fees in Exchange for Excluding Lower Cost Drug Products, FTC File No. P221201 (June 16, 2022), https://www.ftc.gov/legal-library/browse/policy-statement-federal-trade-commission-rebates-fees-exchange-excluding-lower-cost-drug-products.

[2] In April 2021 the Supreme Court held that Section 13(b) of the FTC Act does not authorize federal courts to require defendants to pay refunds to harmed consumers or give up the unjust gains they earned from breaking the law. *AMG Capital Mgmt., LLC. v. FTC*, 141 S. Ct. 1341 (2021). The federal court path now foreclosed had been used for forty years to make injured consumers whole and prevent wrongdoers from profiting from their unlawful conduct. The Commission's loss of its ability to obtain monetary relief under 13(b) has already had a profound effect

two-thirds of what it was at the beginning of 1980, even as the nation's GDP has increased six-fold. Demands on the Commission continue to grow as we receive more consumer complaints, review more corporate mergers, conduct more complex and expensive litigation, and respond to burgeoning requests for research and investigation of various economic sectors. While we constantly strive to enforce the law to the best of our capabilities, there is no doubt that despite the increased appropriations Congress has provided in recent years, we continue to lack sufficient funding. I look forward to working with Congress to ensure that the Commission has the resources and tools it needs to vigorously protect Americans from unlawful business practices throughout the economy.

Thank you again for raising this topic and your vigilance in promoting fair competition. If you or your staff have any questions, please contact Jeanne Bumpus, the Director of the FTC's Office of Congressional Relations, at (202) 326-2195.

Sincerely,

Lina Khan

Lina M. Khan
Chair, Federal Trade Commission

on consumers and honest businesses: by conservative estimates, this court decision has caused consumers to already lose out on more than $1.5 billion of relief that the agency previously could have obtained under Section 13(b), and the losses increase with each passing day.

UNITED STATES OF AMERICA
Federal Trade Commission
WASHINGTON, D.C. 20580

Office of the Chair

November 8, 2022

The Honorable Charles E. Grassley
United States Senate
Washington, D.C. 20510

Dear Senator Grassley:

Thank you for your October 6, 2022 letter supporting the Federal Trade Commission's recently launched study of certain pharmacy benefit manager ("PBM") industry practices and requesting the timely completion of that study as well as the timely issuance of a report of the study's findings.

I view this inquiry as a critical step in more closely scrutinizing business practices across the pharmaceutical supply chain that can raise drug prices, limit access for patients, and contribute to the shuttering of independent pharmacies across the country. If we find evidence of any illegal practices—be it unfair methods of competition or unfair or deceptive practices—I will strive to ensure that the FTC vigorously brings our full authorities to bear in response.

Given that PBMs' practices can have life-and-death consequences for Americans, we are striving to complete the study and issue a report on it as soon as possible. But we are also considering other tools, such as law enforcement, to combat any unlawful PBM practices. In June 2022, we issued a policy statement that lays out concerns about certain business practices that may be resulting in Americans having to pay higher prices for essential medicines, including insulin.[1] The policy statement notes that the FTC has a variety of statutory authorities that it can apply to assess whether those practices may be illegal.

I also want to take this opportunity to ask for your support for two measures essential for a vigorous FTC that can fully protect Americans from unlawful business practices: (1) restoring the Commission's full authority to return money to victimized consumers;[2] and (2) providing the Commission with the funding necessary for us to fulfill our vital mission. The Commission's

[1] Press Release, Fed. Trade Comm'n, FTC to Ramp Up Enforcement Against Any Illegal Rebate Schemes, Bribes to Prescription Drug Middleman That Block Cheaper Drugs (Jun. 16, 2022), https://www.ftc.gov/news-events/news/press-releases/2022/06/ftc-ramp-up-enforcement-against-illegal-rebate-schemes; *see also* Fed. Trade Comm'n, Policy Statement of the Federal Trade Commission on Rebates and Fees in Exchange for Excluding Lower Cost Drug Products, FTC File No. P221201 (June 16, 2022), https://www.ftc.gov/legal-library/browse/policy-statement-federal-trade-commission-rebates-fees-exchange-excluding-lower-cost-drug-products.

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loss of its ability to obtain monetary relief under 13(b) of the FTC Act has already had a profound effect on consumers and honest businesses: by conservative estimates, this court decision has caused consumers to already lose out on more than $1.5 billion of relief that the agency previously could have obtained under Section 13(b), and the losses increase with each passing day.[3]

As for funding, despite having a broad mandate from Congress and being on the front lines of many of the most pressing issues Americans face today, the agency's funding has not kept up with the additional demands on its resources. Indeed, the number of full-time employees at the FTC is about two-thirds of what it was at the beginning of 1980, even as the nation's GDP has increased six-fold. Demands on the Commission continue to grow as we receive more consumer complaints, review more corporate mergers, conduct more complex and expensive litigation, and respond to burgeoning requests for research and investigation of various economic sectors. While we constantly strive to enforce the law to the best of our capabilities, there is no doubt that despite the increased appropriations Congress has provided in recent years, we continue to lack sufficient funding. I look forward to working with Congress to ensure that the Commission has the resources and tools it needs to vigorously protect Americans from unlawful business practices throughout the economy.

Thank you again for raising this topic and your vigilance in promoting fair competition in the drug industry. If you or your staff have any questions, please contact Jeanne Bumpus, the Director of the FTC's Office of Congressional Relations, at (202) 326-2195.

Sincerely,

Lina Khan

Lina M. Khan
Chair, Federal Trade Commission

[3] Statement of Commissioner Rebecca Kelly Slaughter Joined by Chair Lina M. Khan Regarding Section 13(b) of the FTC Act (Apr. 28, 2022), https://www.ftc.gov/system/files/ftc_gov/pdf/Statement%20of%20Comm%27r%20Slaughter%20Joined%20by%20Chair%20Khan%20Regarding%20Section%2013%28b%29%20of%20the%20FTC%20Act_April%202022.pdf.

UNITED STATES OF AMERICA
Federal Trade Commission
WASHINGTON, D.C. 20580

Office of the Chair

November 8, 2022

The Honorable Cindy Hyde-Smith
United States Senate
Washington, D.C. 20510

Dear Senator Hyde-Smith:

Thank you for your October 6, 2022 letter supporting the Federal Trade Commission's recently launched study of certain pharmacy benefit manager ("PBM") industry practices and requesting the timely completion of that study as well as the timely issuance of a report of the study's findings.

I view this inquiry as a critical step in more closely scrutinizing business practices across the pharmaceutical supply chain that can raise drug prices, limit access for patients, and contribute to the shuttering of independent pharmacies across the country. If we find evidence of any illegal practices—be it unfair methods of competition or unfair or deceptive practices—I will strive to ensure that the FTC vigorously brings our full authorities to bear in response.

Given that PBMs' practices can have life-and-death consequences for Americans, we are striving to complete the study and issue a report on it as soon as possible. But we are also considering other tools, such as law enforcement, to combat any unlawful PBM practices. In June 2022, we issued a policy statement that lays out concerns about certain business practices that may be resulting in Americans having to pay higher prices for essential medicines, including insulin.[1] The policy statement notes that the FTC has a variety of statutory authorities that it can apply to assess whether those practices may be illegal.

I also want to take this opportunity to ask for your support for two measures essential for a vigorous FTC that can fully protect Americans from unlawful business practices: (1) restoring the Commission's full authority to return money to victimized consumers;[2] and (2) providing the Commission with the funding necessary for us to fulfill our vital mission. The Commission's

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As for funding, despite having a broad mandate from Congress and being on the front lines of many of the most pressing issues Americans face today, the agency's funding has not kept up with the additional demands on its resources. Indeed, the number of full-time employees at the FTC is about two-thirds of what it was at the beginning of 1980, even as the nation's GDP has increased six-fold. Demands on the Commission continue to grow as we receive more consumer complaints, review more corporate mergers, conduct more complex and expensive litigation, and respond to burgeoning requests for research and investigation of various economic sectors. While we constantly strive to enforce the law to the best of our capabilities, there is no doubt that despite the increased appropriations Congress has provided in recent years, we continue to lack sufficient funding. I look forward to working with Congress to ensure that the Commission has the resources and tools it needs to vigorously protect Americans from unlawful business practices throughout the economy.

Thank you again for raising this topic and your vigilance in promoting fair competition in the drug industry. If you or your staff have any questions, please contact Jeanne Bumpus, the Director of the FTC's Office of Congressional Relations, at (202) 326-2195.

Sincerely,

Lina Khan

Lina M. Khan
Chair, Federal Trade Commission

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UNITED STATES OF AMERICA
Federal Trade Commission
WASHINGTON, D.C. 20580

Office of the Chair

November 8, 2022

The Honorable James Lankford
United States Senate
Washington, D.C. 20510

Dear Senator Lankford:

Thank you for your October 6, 2022 letter supporting the Federal Trade Commission's recently launched study of certain pharmacy benefit manager ("PBM") industry practices and requesting the timely completion of that study as well as the timely issuance of a report of the study's findings.

I view this inquiry as a critical step in more closely scrutinizing business practices across the pharmaceutical supply chain that can raise drug prices, limit access for patients, and contribute to the shuttering of independent pharmacies across the country. If we find evidence of any illegal practices—be it unfair methods of competition or unfair or deceptive practices—I will strive to ensure that the FTC vigorously brings our full authorities to bear in response.

Given that PBMs' practices can have life-and-death consequences for Americans, we are striving to complete the study and issue a report on it as soon as possible. But we are also considering other tools, such as law enforcement, to combat any unlawful PBM practices. In June 2022, we issued a policy statement that lays out concerns about certain business practices that may be resulting in Americans having to pay higher prices for essential medicines, including insulin.[1] The policy statement notes that the FTC has a variety of statutory authorities that it can apply to assess whether those practices may be illegal.

I also want to take this opportunity to ask for your support for two measures essential for a vigorous FTC that can fully protect Americans from unlawful business practices: (1) restoring the Commission's full authority to return money to victimized consumers;[2] and (2) providing the Commission with the funding necessary for us to fulfill our vital mission. The Commission's

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loss of its ability to obtain monetary relief under 13(b) of the FTC Act has already had a profound effect on consumers and honest businesses: by conservative estimates, this court decision has caused consumers to already lose out on more than $1.5 billion of relief that the agency previously could have obtained under Section 13(b), and the losses increase with each passing day.[3]

As for funding, despite having a broad mandate from Congress and being on the front lines of many of the most pressing issues Americans face today, the agency's funding has not kept up with the additional demands on its resources. Indeed, the number of full-time employees at the FTC is about two-thirds of what it was at the beginning of 1980, even as the nation's GDP has increased six-fold. Demands on the Commission continue to grow as we receive more consumer complaints, review more corporate mergers, conduct more complex and expensive litigation, and respond to burgeoning requests for research and investigation of various economic sectors. While we constantly strive to enforce the law to the best of our capabilities, there is no doubt that despite the increased appropriations Congress has provided in recent years, we continue to lack sufficient funding. I look forward to working with Congress to ensure that the Commission has the resources and tools it needs to vigorously protect Americans from unlawful business practices throughout the economy.

Thank you again for raising this topic and your vigilance in promoting fair competition in the drug industry. If you or your staff have any questions, please contact Jeanne Bumpus, the Director of the FTC's Office of Congressional Relations, at (202) 326-2195.

Sincerely,

Lina Khan

Lina M. Khan
Chair, Federal Trade Commission

[3] Statement of Commissioner Rebecca Kelly Slaughter Joined by Chair Lina M. Khan Regarding Section 13(b) of the FTC Act (Apr. 28, 2022), https://www.ftc.gov/system/files/ftc_gov/pdf/Statement%20of%20Comm%27r%20Slaughter%20Joined%20by%20Chair%20Khan%20Regarding%20Section%2013%28b%29%20of%20the%20FTC%20Act_April%202022.pdf.

UNITED STATES OF AMERICA
Federal Trade Commission
WASHINGTON, D.C. 20580

Office of the Chair

November 8, 2022

The Honorable Jerry Moran
United States Senate
Washington, D.C. 20510

Dear Senator Moran:

Thank you for your October 6, 2022 letter supporting the Federal Trade Commission's recently launched study of certain pharmacy benefit manager ("PBM") industry practices and requesting the timely completion of that study as well as the timely issuance of a report of the study's findings.

I view this inquiry as a critical step in more closely scrutinizing business practices across the pharmaceutical supply chain that can raise drug prices, limit access for patients, and contribute to the shuttering of independent pharmacies across the country. If we find evidence of any illegal practices—be it unfair methods of competition or unfair or deceptive practices—I will strive to ensure that the FTC vigorously brings our full authorities to bear in response.

Given that PBMs' practices can have life-and-death consequences for Americans, we are striving to complete the study and issue a report on it as soon as possible. But we are also considering other tools, such as law enforcement, to combat any unlawful PBM practices. In June 2022, we issued a policy statement that lays out concerns about certain business practices that may be resulting in Americans having to pay higher prices for essential medicines, including insulin.[1] The policy statement notes that the FTC has a variety of statutory authorities that it can apply to assess whether those practices may be illegal.

I also want to take this opportunity to ask for your support for two measures essential for a vigorous FTC that can fully protect Americans from unlawful business practices: (1) restoring the Commission's full authority to return money to victimized consumers;[2] and (2) providing the Commission with the funding necessary for us to fulfill our vital mission. The Commission's

[1] Press Release, Fed. Trade Comm'n, FTC to Ramp Up Enforcement Against Any Illegal Rebate Schemes, Bribes to Prescription Drug Middleman That Block Cheaper Drugs (Jun. 16, 2022), https://www.ftc.gov/news-events/news/press-releases/2022/06/ftc-ramp-up-enforcement-against-illegal-rebate-schemes; *see also* Fed. Trade Comm'n, Policy Statement of the Federal Trade Commission on Rebates and Fees in Exchange for Excluding Lower Cost Drug Products, FTC File No. P221201 (June 16, 2022), https://www.ftc.gov/legal-library/browse/policy-statement-federal-trade-commission-rebates-fees-exchange-excluding-lower-cost-drug-products.

[2] In April 2021 the Supreme Court held that Section 13(b) of the FTC Act does not authorize federal courts to require defendants to pay refunds to harmed consumers or give up the unjust gains they earned from breaking the law. *AMG Capital Mgmt., LLC. v. FTC*, 141 S. Ct. 1341 (2021).

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Thank you again for raising this topic and your vigilance in promoting fair competition in the drug industry. If you or your staff have any questions, please contact Jeanne Bumpus, the Director of the FTC's Office of Congressional Relations, at (202) 326-2195.

Sincerely,

Lina Khan

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UNITED STATES OF AMERICA
Federal Trade Commission
WASHINGTON, D.C. 20580

Office of the Chair

November 8, 2022

The Honorable Thom Tillis
United States Senate
Washington, D.C. 20510

Dear Senator Tillis:

Thank you for your October 6, 2022 letter supporting the Federal Trade Commission's recently launched study of certain pharmacy benefit manager ("PBM") industry practices and requesting the timely completion of that study as well as the timely issuance of a report of the study's findings.

I view this inquiry as a critical step in more closely scrutinizing business practices across the pharmaceutical supply chain that can raise drug prices, limit access for patients, and contribute to the shuttering of independent pharmacies across the country. If we find evidence of any illegal practices—be it unfair methods of competition or unfair or deceptive practices—I will strive to ensure that the FTC vigorously brings our full authorities to bear in response.

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Congress of the United States
Washington, DC 20515

May 16, 2022

VIA ELECTRONIC TRANSMISSION

The Honorable Lina M. Khan
Chair
Federal Trade Commission
Washington, D.C. 20580

Re: FTC-2022-0015-0001
Solicitation for Public Comments on the Business Practices of Pharmacy Benefit Managers and their Impact on Independent Pharmacies and Consumers

Dear Chair Khan:

We write to you today regarding the Federal Trade Commission's (FTC) Solicitation for Public Comments on the Business Practices of Pharmacy Benefit Managers and their Impact on Independent Pharmacies and Consumers, document identification FTC-2022-0015-0001. Please submit this letter on the public record as a formal comment submitted by Senators Charles Grassley, Ron Wyden, and Mike Braun.

I. Background

On January 14, 2021, Senator Grassley and Senator Wyden released an 88-page bipartisan staff report titled, "Insulin: Examining the Factors Driving the Rising Cost of a Century Old Drug."[1] Our report provides a comprehensive overview of the Senate Finance Committee's nearly two-year investigation into how the three largest insulin manufacturers—Sanofi, Novo Nordisk, and Eli Lilly—and the three largest pharmacy benefit managers (PBM)—OptumRx, Express Scripts, and CVS Caremark—price insulin medication. We reviewed more than 100,000 pages of internal company documents and exposed the behind the scenes negotiations that take place between insulin manufacturers and PBMs. Information and documents collected during this investigation suggest that a combination of factors contribute to patients facing higher costs for insulin.[2] Most notably, however, the practice of offering rebates, discounts, and other fees to PBMs

[1] STAFF OF S. FIN. COMM, 116TH CONGRESS, INSULIN: EXAMINING THE FACTORS DRIVING THE RISING COST OF A CENTURY OLD DRUG (COMM. PRINT 2021), https://www.finance.senate.gov/imo/media/doc/Insulin%20Committee%20Print.pdf.
[2] STAFF OF S. FIN. COMM, 116TH CONGRESS, INSULIN: EXAMINING THE FACTORS DRIVING THE RISING COST OF A CENTURY OLD DRUG (COMM. PRINT 2021), https://www.finance.senate.gov/imo/media/doc/Insulin%20Committee%20Print.pdf.

to secure preferred formulary placement seems to be connected to increasing wholesale acquisition price (WAC), known colloquially as "list price." The materials we reviewed showed that such list price increases benefitted both PBMs and manufacturers, to the detriment of consumers.

We initiated this investigation for several reasons. At the time, it was widely reported that Americans living with diabetes were rationing their insulin medication, or forgoing it entirely, because of the drug's high list price—practices that can lead to blindness, kidney failure, diabetic ketoacidosis, or even death.[3] For example, during the Committee's hearing titled *Drug Pricing in America: A Prescription for Change, Part 1*, we heard testimony from Kathy Sego, a resident of Indiana and mother whose son has Type 1 diabetes.[4] According to Ms. Sego, unbeknownst to her, her son began rationing his insulin in order for his family to afford the $1,700 monthly price tag.[5] Unfortunately, Ms. Sego's family is not alone in this struggle.

As of 2019, more than 37 million Americans live with diabetes.[6] Of this figure, more than 7 million use insulin on a daily basis.[7] Diabetes disproportionally affects communities of color and those who live in rural communities. According to the CDC, the prevalence of diagnosed diabetes is highest among American Indians, Hispanics, and Black Americans.[8] Recent research also suggests a surge in diabetes among American's youth as well.[9] The science is clear—this disease will play a role in the health of Americans for years and decades to come.

With these health disparities at the forefront of public discourse, we became concerned that the market power and opaque business practices of PBMs were affecting insulins' list prices. As you know, PBMs manage the prescription drug benefit on behalf of health insurers and other payers, including employer-sponsored health plans and the Federal government.[10] Through mergers and acquisitions, just three PBMs—OptumRx, Express Scripts, and CVS Caremark—

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[3] Tiffany Stanley, *Life, Death, and Insulin, As the cost of the lifesaving mediation skyrockets, some desperate diabetics are rationing – and risking their lives. Was Alex Raeshawn Smith one of them?* THE WASH. POST. (Jan. 7, 2019), https://www.washingtonpost.com/news/magazine/wp/2019/01/07/feature/insulin-is-a-lifesaving-drug-but-it-has-become-intolerably-expensive-and-the-consequences-can-be-tragic; Alexa Lardieri, *Study: Almost half of diabetics skip care because of high cost*, U.S. NEWS (June 18, 2018), https://www.usnews.com/news/health-care-news/articles/2018-06-18/study-almost-half-of-diabetics-skip-care-because-of-high-cost/.

[4] *Drug Pricing in America: A Prescription for Change Part I, Hearing Before the S. Fin. Comm., 106th Cong.* (2019) (statement of Kathy Sego), https://www.finance.senate.gov/download/segotestimony.

[5] *Drug Pricing in America: A Prescription for Change Part I, Hearing Before the S. Fin. Comm., 106th Cong.* (2019) (statement of Kathy Sego), https://www.finance.senate.gov/download/segotestimony.

[6] *The Facts, Stats, and Impacts of Diabetes*, CDC https://www.cdc.gov/diabetes/library/spotlights/diabetes-facts-stats.html#:~:text=Key%20findings%20include%3A,t%20know%20they%20have%20it (last reviewed Jan. 24, 2022).

[7] *Drug Pricing in America: A Prescription for Change Part I, Hearing Before the S. Fin. Comm., 106th Cong.* (2019) (statement of Kathy Sego), https://www.finance.senate.gov/download/segotestimony.

[8] *Prevalence of diagnosed diabetes*, CDC, https://www.cdc.gov/diabetes/data/statistics-report/diagnosed-diabetes.html (last reviewed Dec. 29, 2021).

[9] *New Research Uncovers Concerning Increases in Youth Living with Diabetes in the U.S.*, CDC (Aug. 24, 2021), https://www.cdc.gov/media/releases/2021/p0824-youth-diabetes.html.

[10] STAFF OF S. FIN. COMM, 116TH CONGRESS, INSULIN: EXAMINING THE FACTORS DRIVING THE RISING COST OF A CENTURY OLD DRUG (COMM. PRINT 2021), at 24, https://www.finance.senate.gov/imo/media/doc/Insulin%20Committee%20Print.pdf.

control more than 80% of drug benefits administered to more than 180 million Americans.[11] PBMs are also vertically integrated with health insurers and operate their own pharmacies.[12] Despite, or perhaps because of, this level of consolidation, PBMs operate with little transparency, making it difficult, if not impossible to understand how PBMs influence prescription drug pricing. This opacity led to the beginning of the Committee's bipartisan investigation in 2019, and it is why Senator Grassley called on the FTC earlier this year to move forward on a revised 6(b) study to examine competitive concerns within the PBM industry.[13]

This letter will provide a brief overview of the Committee's investigative findings, explain how the business practices of PBMs influence list price especially in the insulin therapeutic class, and describe how these practices affect patients, payers, and the Federal government. We are also attaching a copy of the Committee's 88-page bipartisan report to this letter. We strongly encourage your staff to read its contents as you formulate your 6(b) study.

II. High List Prices Appear to Be Related to Certain PBM Contracting Practices

During the Committee's nearly two-year bipartisan investigation, PBMs argued that they work to obtain the lowest net price for their clients (or, the price realized by the health plan after deducting rebates, discounts, and other fees) and that manufacturers are, "solely responsible for the high cost of prescription drugs."[14] Manufacturers on the other hand argued PBMs "favor products with high list prices and deep rebates" to attract and retain clients and that rebates do not directly benefit patients.[15] During the Committee's investigation, we found that certain contracting practices create incentives for PBMs to favor drugs with high list prices and high rebates, which discourages manufacturers from competing to lower list prices.[16] We also found that insulin is

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[11] STAFF OF S. FIN. COMM, 116TH CONGRESS, INSULIN: EXAMINING THE FACTORS DRIVING THE RISING COST OF A CENTURY OLD DRUG (COMM. PRINT 2021), at 24-29, https://www.finance.senate.gov/imo/media/doc/Insulin%20Committee%20Print.pdf.

[12] STAFF OF S. FIN. COMM, 116TH CONGRESS, INSULIN: EXAMINING THE FACTORS DRIVING THE RISING COST OF A CENTURY OLD DRUG (COMM. PRINT 2021), at 24-25, https://www.finance.senate.gov/imo/media/doc/Insulin%20Committee%20Print.pdf.

[13] Press Release, Grassley, Wyden Release Insulin Investigation, Uncovering Business Practices Between Drug Companies and PBMs that Keep Prices High (Jan. 14, 2021), https://www.finance.senate.gov/chairmans-news/grassley-wyden-release-insulin-investigation-uncovering-business-practices-between-drug-companies-and-pbms-that-keep-prices-high; Press Release, Grassley Presses FTC to Investigate Pharmacy Benefit Mangers' Role in Consumer Drug Prices (Mar. 10, 2022), https://www.grassley.senate.gov/news/news-releases/grassley-presses-ftc-to-investigate-pharmacy-benefit-managers-role-in-consumer-drug-prices.

[14] *Drug Pricing in America: A Prescription for Change Part III, Hearing Before the S. Fin. Comm., 106th Cong.* (2019) (statement of John M. Prince, Chief Executive Officer, OptumRx), https://www.finance.senate.gov/imo/media/doc/435631.pdf.

[15] *Drug Pricing in America: A Prescription for Change Part II, Hearing Before the S. Fin. Comm., 106th Cong.* (2019) (in response to questions submitted for the record by Sen. Menendez), https://www.finance.senate.gov/imo/media/doc/37143.pdf; *Drug Pricing in America: A Prescription for Change Part II, Hearing Before the S. Fin. Comm., 106th Cong.* (2019) (statement of Albert Bourla, Ph.D., Chief Executive Officer, Pfizer), https://www.finance.senate.gov/imo/media/doc/37143.pdf.

[16] STAFF OF S. FIN. COMM, 116TH CONGRESS, INSULIN: EXAMINING THE FACTORS DRIVING THE RISING COST OF A CENTURY OLD DRUG (COMM. PRINT 2021), at 63, https://www.finance.senate.gov/imo/media/doc/Insulin%20Committee%20Print.pdf.

unaffordable for many Americans, especially those with high-deductible health plans, those who are underinsured, or those who have no insurance.[17]

a. PBM Contracting Practices: Rebates, Formulary Exclusion Lists, Administrative Fees, and Price Protection Clauses

Rebates have increased in lock step with list price since at least 2013. For example, internal company documents collected for the Committee's investigation show that, in 2013, average rebates for long-acting insulin products hovered around 2% and 4% for preferred formulary placement.[18] However, approximately six years later, rebates for the same product were as high as 79.75%.[19] [It's important to note that rebates vary by product, payer, and placement on a plan's formulary. However, in the insulin therapeutic class, we found that PBMs with a large volume of clients are able to extract higher rebates from manufacturers when compared to smaller payers, who often lack leverage and resources.[20]] WAC data collected for the Committee's investigation also suggest list prices for long-acting and short-acting insulins have increased rapidly during this same period. For example:

- Sanofi's Lantus SoloStar (pens) increased from a WAC of $303 in January 2014 to approximately $404 in January 2019—an increase of over 33% in 5 years.[207]
- Novo Nordisk's Levemir Flextouch (pens) increased from a WAC of $303 in May 2014 to approximately $462 in January 2019—an increase of over 52% in 5 years.[208]
- Eli Lilly's Basaglar launched in November 2016 with a WAC price 23% *lower* than Lantus at $316.85.[209] However, Basaglar's WAC price increased to $326.36 the following year.[210]

[21]

As list price and rebates have increased in the insulin therapeutic class, the cost to patients and the Federal government has ballooned. Based on data provided by the Centers for Medicare and Medicaid Services (CMS), annual spending on insulin has increased by billions of dollars over the past decade. Between 2010 and 2018, Medicare Part D spent $78.4 billion prior to rebates.[22]

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[17] STAFF OF S. FIN. COMM, 116TH CONGRESS, INSULIN: EXAMINING THE FACTORS DRIVING THE RISING COST OF A CENTURY OLD DRUG (COMM. PRINT 2021), at 10-12, https://www.finance.senate.gov/imo/media/doc/Insulin%20Committee%20Print.pdf.

[18] STAFF OF S. FIN. COMM, 116TH CONGRESS, INSULIN: EXAMINING THE FACTORS DRIVING THE RISING COST OF A CENTURY OLD DRUG (COMM. PRINT 2021), at 60, https://www.finance.senate.gov/imo/media/doc/Insulin%20Committee%20Print.pdf.

[19] STAFF OF S. FIN. COMM, 116TH CONGRESS, INSULIN: EXAMINING THE FACTORS DRIVING THE RISING COST OF A CENTURY OLD DRUG (COMM. PRINT 2021), at 60, https://www.finance.senate.gov/imo/media/doc/Insulin%20Committee%20Print.pdf.

[20] STAFF OF S. FIN. COMM, 116TH CONGRESS, INSULIN: EXAMINING THE FACTORS DRIVING THE RISING COST OF A CENTURY OLD DRUG (COMM. PRINT 2021), at 62, https://www.finance.senate.gov/imo/media/doc/Insulin%20Committee%20Print.pdf.

[21] STAFF OF S. FIN. COMM, 116TH CONGRESS, INSULIN: EXAMINING THE FACTORS DRIVING THE RISING COST OF A CENTURY OLD DRUG (COMM. PRINT 2021), at 37, https://www.finance.senate.gov/imo/media/doc/Insulin%20Committee%20Print.pdf.

[22] STAFF OF S. FIN. COMM, 116TH CONGRESS, INSULIN: EXAMINING THE FACTORS DRIVING THE RISING COST OF A CENTURY OLD DRUG (COMM. PRINT 2021), at 40, https://www.finance.senate.gov/imo/media/doc/Insulin%20Committee%20Print.pdf.

Patients' costs for insulin have also soared. Based on Medicare Part D gross drug cost data, in 2018, more than a quarter of patients enrolled in Medicare Part D spent upwards of $5,000 a year on their insulin medications.[23] This is why the Federal government must continue to take steps to lessen the financial burden of Americans living with diabetes, including investigating ways in which certain business practices impact list price.[24]

We found that a manufacturer's decision to increase insulin's list price was influenced, in part, by certain PBM contracting practices. For example, beginning in 2012, payers and PBMs increased their use of formulary exclusion lists to control drug costs.[25] When a drug is excluded from a formulary, it means the drug will not be covered by insurance unless an exception is granted for the patient.[26] Exclusion can have significant consequences for patients and manufacturers. For patients, if a drug is excluded from coverage, they are forced to either switch to another product or pay significantly more to stay on their preferred medication.[27] For manufacturers, exclusion can result in significant financial loss and reduced market share.[28] Indeed, the Committee's investigation found several instances where manufacturers increased their rebate offers to PBMs significantly following the threat of exclusion, which appears to have contributed to higher list prices.

Other PBM contracting practices also appear to embolden high list prices. For example, PBMs earn an administrative fee for each unit of a manufacturer's drug dispensed at the pharmacy counter.[29] These fees, which are calculated as a percentage off WAC, are negotiated between the PBM and manufacturer to cover costs related to the rebate program like monitoring their client's compliance with rebate eligibility requirements and preparing reports on product utilization.[30] The amount of administrative fees paid industry-wide is not well known because this information is contained in confidential rebate agreements and not disclosed by PBMs. However, information

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[23] STAFF OF S. FIN. COMM, 116TH CONGRESS, INSULIN: EXAMINING THE FACTORS DRIVING THE RISING COST OF A CENTURY OLD DRUG (COMM. PRINT 2021), at 42, https://www.finance.senate.gov/imo/media/doc/Insulin%20Committee%20Print.pdf.

[24] Senator Grassley's Prescription Drug Price Reduction Act (PDPRA) of 2019 is one such example where Congress can take meaningful action to lower drug costs for seniors. PDPRA modernizes Medicare Part D, limits patients' out-of-pocket costs, and penalizes manufacturers who raise list price higher than inflation. This bill was discharged by the Senate Finance Committee in a bipartisan vote (19-9) in July 2019.

[25] STAFF OF S. FIN. COMM, 116TH CONGRESS, INSULIN: EXAMINING THE FACTORS DRIVING THE RISING COST OF A CENTURY OLD DRUG (COMM. PRINT 2021), at 63, https://www.finance.senate.gov/imo/media/doc/Insulin%20Committee%20Print.pdf.

[26] STAFF OF S. FIN. COMM, 116TH CONGRESS, INSULIN: EXAMINING THE FACTORS DRIVING THE RISING COST OF A CENTURY OLD DRUG (COMM. PRINT 2021), at 66, https://www.finance.senate.gov/imo/media/doc/Insulin%20Committee%20Print.pdf.

[27] STAFF OF S. FIN. COMM, 116TH CONGRESS, INSULIN: EXAMINING THE FACTORS DRIVING THE RISING COST OF A CENTURY OLD DRUG (COMM. PRINT 2021), at 66, https://www.finance.senate.gov/imo/media/doc/Insulin%20Committee%20Print.pdf.

[28] STAFF OF S. FIN. COMM, 116TH CONGRESS, INSULIN: EXAMINING THE FACTORS DRIVING THE RISING COST OF A CENTURY OLD DRUG (COMM. PRINT 2021), at 66, https://www.finance.senate.gov/imo/media/doc/Insulin%20Committee%20Print.pdf.

[29] STAFF OF S. FIN. COMM, 116TH CONGRESS, INSULIN: EXAMINING THE FACTORS DRIVING THE RISING COST OF A CENTURY OLD DRUG (COMM. PRINT 2021), at 72, https://www.finance.senate.gov/imo/media/doc/Insulin%20Committee%20Print.pdf.

[30] STAFF OF S. FIN. COMM, 116TH CONGRESS, INSULIN: EXAMINING THE FACTORS DRIVING THE RISING COST OF A CENTURY OLD DRUG (COMM. PRINT 2021), at 73, https://www.finance.senate.gov/imo/media/doc/Insulin%20Committee%20Print.pdf.

collected for this investigation suggests that, in the insulin therapeutic class, administrative fees are between 3% and 5% of WAC.[31] Administrative fees appear problematic because manufacturers are willing to increase list price in order to offer PBMs these additional concessions to secure preferred formulary placement. As one law review article explained it, when discussing administrative fees in the context of PBMs:

> "[T]hese payments reduce the drug company's net income from sales of the drug and increase the PBM revenue related to a specific drug. Even when a drug company pays for services from a PBM, if the value of the service is substantially less than the payment made, the transaction is simply an indirect price concession. Once again, raising list price can leave room for the drug company to offer these goodies . . . [and, as a result], many people be will be forced to pay higher list prices."[32]

In addition to rebates and administrative fees, PBMs also negotiate price protection clauses. Price protection clauses are meant to limit a drug manufacturer from increasing list price beyond an agreed upon percentage.[33] If the manufacturer increases the list price beyond the agreed upon percentage, the PBM and health plan receive an additional rebate depending on the terms of the contract.[34] Based on the Committee's investigation, price protection clauses do not deter annual inflation of a manufacturer's list price.[35] Instead, PBMs accept list price increases as long as they continue to secure more and more price concessions for themselves and their clients.

III. Conclusion

We found that PBM contracting practices do little to discourage high list prices, especially in the insulin therapeutic class. In fact, this perverse system exacerbates the problem by discouraging manufacturers from competing to lower list price and prevents competitors with lower priced alternatives from gaining a foothold. This prevents meaningful competition, harming taxpayers and the Federal government in the process. This is why it is important that the FTC conduct a 6(b) study and review the ways in which PBMs serve as the gate keepers for prescription

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[31] STAFF OF S. FIN. COMM, 116TH CONGRESS, INSULIN: EXAMINING THE FACTORS DRIVING THE RISING COST OF A CENTURY OLD DRUG (COMM. PRINT 2021), at 74, https://www.finance.senate.gov/imo/media/doc/Insulin%20Committee%20Print.pdf.

[32] Robin Feldman, *Perverse Incentives: Why Everyone Prefers High Drug Prices—Except for Those Who Pay the Bills*, 57 HARV. J. ON LEGIS. 303, 328 (2020).

[33] STAFF OF S. FIN. COMM, 116TH CONGRESS, INSULIN: EXAMINING THE FACTORS DRIVING THE RISING COST OF A CENTURY OLD DRUG (COMM. PRINT 2021), at 75-76, https://www.finance.senate.gov/imo/media/doc/Insulin%20Committee%20Print.pdf.

[34] STAFF OF S. FIN. COMM, 116TH CONGRESS, INSULIN: EXAMINING THE FACTORS DRIVING THE RISING COST OF A CENTURY OLD DRUG (COMM. PRINT 2021), at 76, https://www.finance.senate.gov/imo/media/doc/Insulin%20Committee%20Print.pdf.

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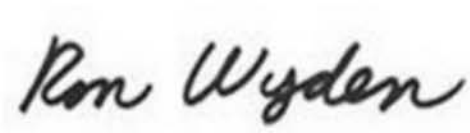
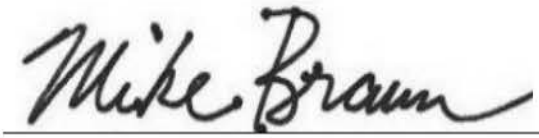
drugs for millions of Americans and how other business practices may harm patients, payers, and the Federal government.[36]

Charles E. Grassley
Ranking Member
Senate Judiciary Committee



Ron Wyden
Chairman
Senate Committee on Finance



Mike Braun
Senator

[36] As the FTC formulates its 6(b) study, it may want to pay special attention to spread pricing, direct and indirect remuneration (DIR), white bagging, and the impact of vertical integration on patients, payers, and the Federal government. There is a dearth of information about these practices, which calls for sunshine-like transparency.

UNITED STATES OF AMERICA
Federal Trade Commission
WASHINGTON, D.C. 20580

Office of the Chair

February 13, 2024

The Honorable Marsha Blackburn
United States Senate
Washington, D.C. 20510

Dear Senator Blackburn:

Thank you for your January 22, 2024, letter and your continued support of the Federal Trade Commission's (FTC) study of certain pharmacy benefit manager (PBM) industry practices. There is appropriately a high degree of public interest in this industry. The industry's practices and their effects remain opaque despite the central role PBMs play in deciding which drugs are prescribed to patients, which pharmacies patients can use, and how much patients ultimately pay at the pharmacy counter. Decisions by PBMs and their affiliates may have a significant impact on patients' ability to access and afford their prescription drugs.

This can have dire consequences for Americans, with nearly three in ten surveyed Americans reporting rationing or even skipping doses of their prescribed medicines due to high costs.[1] PBMs also have substantial influence over independent pharmacies, which have collectively voiced concern that PBMs impose contractual terms with these pharmacies that are confusing, unfair, arbitrary, and harmful to their businesses.

Given the importance of this industry and troubling reports about PBM practices, I share your sense of urgency regarding timely completion of the study and welcome this opportunity to provide you an interim progress update on our ongoing study of this industry.

As you know, in June 2022, the FTC issued Orders to PBMs pursuant to its 6(b) authority to study a range of PBM business practices that may affect drug affordability and access.[2] The Order requires the six largest PBMs—Caremark Rx, LLC; Express Scripts, Inc.; OptumRx, Inc.; Humana Pharmacy Solutions, Inc.; Prime Therapeutics LLC; and MedImpact Healthcare Systems, Inc.—to provide data and documents regarding certain business practices. This inquiry

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builds on the more than 1,200 public comments[3] the Commission received in response to a request for information about PBMs that the agency issued on February 24, 2022.[4]

The PBM 6(b) inquiry seeks to examine several of the most common and serious complaints about PBMs. Our inquiry is aimed at shedding light on several business practices that have drawn public scrutiny in recent years, including: fees and clawbacks charged to unaffiliated pharmacies; methods to steer patients towards PBM-affiliated pharmacies; potentially unfair audits of independent pharmacies; complicated and opaque methods to determine pharmacy reimbursement; the prevalence of prior authorizations and other administrative restrictions; the use of specialty drug lists and surrounding specialty drug policies; and the impact of rebates and fees from drug manufacturers on formulary design and the costs of prescription drugs to payers and patients.

In May and June 2023, the FTC expanded its PBM study by issuing three additional compulsory orders to companies that perform rebate services for their affiliated PBMs.[5] These additional 6(b) Orders require the three group purchasing organizations (GPO) that are linked to the six largest PBMs—Zinc Health Services, LLC, Ascent Health Services, LLC, and Emisar Pharma Services LLC —to produce documents. These GPOs, also called rebate aggregators, negotiate rebates with drug manufacturers on behalf of the PBMs and hold the contracts that govern those rebates. Zinc was founded in 2020 and operates as the GPO for CVS Caremark. Ascent was founded in 2019 and operates as the GPO for Express Scripts, Prime Therapeutics, Envolve Pharmacy Solutions, and Humana Pharmacy Solutions. Emisar, like Zinc and Ascent, negotiates rebates with drug manufacturers. Emisar negotiates rebates on behalf of OptumRx and, like OptumRx, is a subsidiary of UnitedHealth Group.

Although our compulsory orders were issued in June 2022, and May and June 2023, to date no company has turned over sufficient documents and data to be in full compliance with those orders. FTC staff continues to push the PBM/GPOs to finalize their production of documents and data required by the Orders as quickly as possible. The respondents have proceeded with varying levels of speed in their productions and compliance with the Orders. We expect to have all the materials very soon. If, however, some of the companies fail to fully comply with the orders or engage in any actionable delaying tactics, the FTC can take them to court to compel compliance.

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This 6(b) inquiry remains one of my top priorities, and I view it as a crucial part of scrutinizing business practices across the pharmaceutical supply chain that can raise drug prices and limit access for patients and that may contribute to the shuttering of independent pharmacies across the country. I share your view that this is a time-sensitive matter of paramount importance, and that we should provide the public and policymakers with as much information about what we are learning and insight about possible competitive harms as quickly as possible. I have asked FTC staff to prioritize doing so to the maximum extent possible, so that dilatory tactics by companies do not prevent us from sharing what we learn in the course of the 6(b) study as quickly as we can. And to be clear: if we find evidence of illegal practices—be it unfair methods of competition or unfair or deceptive practices—I will prioritize bringing the Commission's full authorities to bear.

Separately, I wanted to take the opportunity to ask for your support for two measures essential for a vigorous FTC that can fully protect Americans from unlawful business practices: (1) providing the Commission with the funding necessary for us to fulfill our vital mission; and (2) restoring the Commission's full authority to return money to victimized consumers.[6]

Demands on the Commission continue to grow and strain the agency's resources and capacity as the FTC conducts more 6(b) studies and our merger review and litigation have become more complex, involving cases against some of the most well-resourced companies in the world. While Congress has charged the Commission with a critical mission, our resources have failed to keep pace. We currently employ fewer staffers than we did in the early 1980s, even though our nation's GDP has increased six-fold over the same period, and the Commission has been forced to make difficult decisions about prioritizing investigations. Additional resources would better equip the Commission to fully pursue its mandate and continue the vital work of promoting competition throughout the economy, including in healthcare markets. I look forward to working with Congress to ensure that the Commission has the resources and tools it needs to vigorously protect Americans from unlawful business practices throughout the economy.

With respect to remedies, the Commission's loss of its ability to obtain monetary relief under Section 13(b) has already had a profound effect on consumers and honest businesses: by conservative estimates, this court decision has caused consumers to already lose out on more than $1.5 billion of relief that the agency previously could have obtained under Section 13(b), and the losses increase with each passing day.[7]

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Thank you again for your letter and continued leadership on this important issue. If you or your staff have any questions, please don't hesitate to contact Jeanne Bumpus, the Director of the FTC's Office of Congressional Relations, at (202) 326-2195.

Sincerely,

Lina Khan

Lina M. Khan
Chair, Federal Trade Commission

UNITED STATES OF AMERICA
Federal Trade Commission
WASHINGTON, D.C. 20580

Office of the Chair

February 13, 2024

The Honorable Maria Cantwell
United States Senate
Washington, D.C. 20510

Dear Senator Cantwell:

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This can have dire consequences for Americans, with nearly three in ten surveyed Americans reporting rationing or even skipping doses of their prescribed medicines due to high costs.[1] PBMs also have substantial influence over independent pharmacies, which have collectively voiced concern that PBMs impose contractual terms with these pharmacies that are confusing, unfair, arbitrary, and harmful to their businesses.

Given the importance of this industry and troubling reports about PBM practices, I share your sense of urgency regarding timely completion of the study and welcome this opportunity to provide you an interim progress update on our ongoing study of this industry.

As you know, in June 2022, the FTC issued Orders to PBMs pursuant to its 6(b) authority to study a range of PBM business practices that may affect drug affordability and access.[2] The Order requires the six largest PBMs—Caremark Rx, LLC; Express Scripts, Inc.; OptumRx, Inc.; Humana Pharmacy Solutions, Inc.; Prime Therapeutics LLC; and MedImpact Healthcare Systems, Inc.—to provide data and documents regarding certain business practices. This inquiry

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Sincerely,

Lina Khan

Lina M. Khan
Chair, Federal Trade Commission

UNITED STATES OF AMERICA
Federal Trade Commission
WASHINGTON, D.C. 20580

Office of the Chair

February 13, 2024

The Honorable Shelley Moore Capito
United States Senate
Washington, D.C. 20510

Dear Senator Capito:

Thank you for your January 22, 2024, letter and your continued support of the Federal Trade Commission's (FTC) study of certain pharmacy benefit manager (PBM) industry practices. There is appropriately a high degree of public interest in this industry. The industry's practices and their effects remain opaque despite the central role PBMs play in deciding which drugs are prescribed to patients, which pharmacies patients can use, and how much patients ultimately pay at the pharmacy counter. Decisions by PBMs and their affiliates may have a significant impact on patients' ability to access and afford their prescription drugs.

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Thank you again for your letter and continued leadership on this important issue. If you or your staff have any questions, please don't hesitate to contact Jeanne Bumpus, the Director of the FTC's Office of Congressional Relations, at (202) 326-2195.

Sincerely,

Lina Khan

Lina M. Khan
Chair, Federal Trade Commission

UNITED STATES OF AMERICA
Federal Trade Commission
WASHINGTON, D.C. 20580

Office of the Chair

February 13, 2024

The Honorable Susan M. Collins
United States Senate
Washington, D.C. 20510

Dear Senator Collins:

Thank you for your January 22, 2024, letter and your continued support of the Federal Trade Commission's (FTC) study of certain pharmacy benefit manager (PBM) industry practices. There is appropriately a high degree of public interest in this industry. The industry's practices and their effects remain opaque despite the central role PBMs play in deciding which drugs are prescribed to patients, which pharmacies patients can use, and how much patients ultimately pay at the pharmacy counter. Decisions by PBMs and their affiliates may have a significant impact on patients' ability to access and afford their prescription drugs.

This can have dire consequences for Americans, with nearly three in ten surveyed Americans reporting rationing or even skipping doses of their prescribed medicines due to high costs.[1] PBMs also have substantial influence over independent pharmacies, which have collectively voiced concern that PBMs impose contractual terms with these pharmacies that are confusing, unfair, arbitrary, and harmful to their businesses.

Given the importance of this industry and troubling reports about PBM practices, I share your sense of urgency regarding timely completion of the study and welcome this opportunity to provide you an interim progress update on our ongoing study of this industry.

As you know, in June 2022, the FTC issued Orders to PBMs pursuant to its 6(b) authority to study a range of PBM business practices that may affect drug affordability and access.[2] The Order requires the six largest PBMs—Caremark Rx, LLC; Express Scripts, Inc.; OptumRx, Inc.; Humana Pharmacy Solutions, Inc.; Prime Therapeutics LLC; and MedImpact Healthcare Systems, Inc.—to provide data and documents regarding certain business practices. This inquiry

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builds on the more than 1,200 public comments[3] the Commission received in response to a request for information about PBMs that the agency issued on February 24, 2022.[4]

The PBM 6(b) inquiry seeks to examine several of the most common and serious complaints about PBMs. Our inquiry is aimed at shedding light on several business practices that have drawn public scrutiny in recent years, including: fees and clawbacks charged to unaffiliated pharmacies; methods to steer patients towards PBM-affiliated pharmacies; potentially unfair audits of independent pharmacies; complicated and opaque methods to determine pharmacy reimbursement; the prevalence of prior authorizations and other administrative restrictions; the use of specialty drug lists and surrounding specialty drug policies; and the impact of rebates and fees from drug manufacturers on formulary design and the costs of prescription drugs to payers and patients.

In May and June 2023, the FTC expanded its PBM study by issuing three additional compulsory orders to companies that perform rebate services for their affiliated PBMs.[5] These additional 6(b) Orders require the three group purchasing organizations (GPO) that are linked to the six largest PBMs—Zinc Health Services, LLC, Ascent Health Services, LLC, and Emisar Pharma Services LLC —to produce documents. These GPOs, also called rebate aggregators, negotiate rebates with drug manufacturers on behalf of the PBMs and hold the contracts that govern those rebates. Zinc was founded in 2020 and operates as the GPO for CVS Caremark. Ascent was founded in 2019 and operates as the GPO for Express Scripts, Prime Therapeutics, Envolve Pharmacy Solutions, and Humana Pharmacy Solutions. Emisar, like Zinc and Ascent, negotiates rebates with drug manufacturers. Emisar negotiates rebates on behalf of OptumRx and, like OptumRx, is a subsidiary of UnitedHealth Group.

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Lina Khan

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Chair, Federal Trade Commission

UNITED STATES OF AMERICA
Federal Trade Commission
WASHINGTON, D.C. 20580

Office of the Chair

February 13, 2024

The Honorable Christopher A. Coons
United States Senate
Washington, D.C. 20510

Dear Senator Coons:

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Sincerely,

Lina Khan

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Chair, Federal Trade Commission

UNITED STATES OF AMERICA
Federal Trade Commission
WASHINGTON, D.C. 20580

Office of the Chair

February 13, 2024

The Honorable Charles E. Grassley
United States Senate
Washington, D.C. 20510

Dear Senator Grassley:

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Thank you again for your letter and continued leadership on this important issue. If you or your staff have any questions, please don't hesitate to contact Jeanne Bumpus, the Director of the FTC's Office of Congressional Relations, at (202) 326-2195.

Sincerely,

Lina Khan

Lina M. Khan
Chair, Federal Trade Commission

UNITED STATES OF AMERICA
Federal Trade Commission
WASHINGTON, D.C. 20580

Office of the Chair

February 13, 2024

The Honorable Mazie K. Hirono
United States Senate
Washington, D.C. 20510

Dear Senator Hirono:

Thank you for your January 22, 2024, letter and your continued support of the Federal Trade Commission's (FTC) study of certain pharmacy benefit manager (PBM) industry practices. There is appropriately a high degree of public interest in this industry. The industry's practices and their effects remain opaque despite the central role PBMs play in deciding which drugs are prescribed to patients, which pharmacies patients can use, and how much patients ultimately pay at the pharmacy counter. Decisions by PBMs and their affiliates may have a significant impact on patients' ability to access and afford their prescription drugs.

This can have dire consequences for Americans, with nearly three in ten surveyed Americans reporting rationing or even skipping doses of their prescribed medicines due to high costs.[1] PBMs also have substantial influence over independent pharmacies, which have collectively voiced concern that PBMs impose contractual terms with these pharmacies that are confusing, unfair, arbitrary, and harmful to their businesses.

Given the importance of this industry and troubling reports about PBM practices, I share your sense of urgency regarding timely completion of the study and welcome this opportunity to provide you an interim progress update on our ongoing study of this industry.

As you know, in June 2022, the FTC issued Orders to PBMs pursuant to its 6(b) authority to study a range of PBM business practices that may affect drug affordability and access.[2] The Order requires the six largest PBMs—Caremark Rx, LLC; Express Scripts, Inc.; OptumRx, Inc.; Humana Pharmacy Solutions, Inc.; Prime Therapeutics LLC; and MedImpact Healthcare Systems, Inc.—to provide data and documents regarding certain business practices. This inquiry

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builds on the more than 1,200 public comments[3] the Commission received in response to a request for information about PBMs that the agency issued on February 24, 2022.[4]

The PBM 6(b) inquiry seeks to examine several of the most common and serious complaints about PBMs. Our inquiry is aimed at shedding light on several business practices that have drawn public scrutiny in recent years, including: fees and clawbacks charged to unaffiliated pharmacies; methods to steer patients towards PBM-affiliated pharmacies; potentially unfair audits of independent pharmacies; complicated and opaque methods to determine pharmacy reimbursement; the prevalence of prior authorizations and other administrative restrictions; the use of specialty drug lists and surrounding specialty drug policies; and the impact of rebates and fees from drug manufacturers on formulary design and the costs of prescription drugs to payers and patients.

In May and June 2023, the FTC expanded its PBM study by issuing three additional compulsory orders to companies that perform rebate services for their affiliated PBMs.[5] These additional 6(b) Orders require the three group purchasing organizations (GPO) that are linked to the six largest PBMs—Zinc Health Services, LLC, Ascent Health Services, LLC, and Emisar Pharma Services LLC —to produce documents. These GPOs, also called rebate aggregators, negotiate rebates with drug manufacturers on behalf of the PBMs and hold the contracts that govern those rebates. Zinc was founded in 2020 and operates as the GPO for CVS Caremark. Ascent was founded in 2019 and operates as the GPO for Express Scripts, Prime Therapeutics, Envolve Pharmacy Solutions, and Humana Pharmacy Solutions. Emisar, like Zinc and Ascent, negotiates rebates with drug manufacturers. Emisar negotiates rebates on behalf of OptumRx and, like OptumRx, is a subsidiary of UnitedHealth Group.

Although our compulsory orders were issued in June 2022, and May and June 2023, to date no company has turned over sufficient documents and data to be in full compliance with those orders. FTC staff continues to push the PBM/GPOs to finalize their production of documents and data required by the Orders as quickly as possible. The respondents have proceeded with varying levels of speed in their productions and compliance with the Orders. We expect to have all the materials very soon. If, however, some of the companies fail to fully comply with the orders or engage in any actionable delaying tactics, the FTC can take them to court to compel compliance.

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Even as FTC staff continues to press the companies to turn over the required documents and data, the team has simultaneously been diligently working through the information and data that we have received, much of it only recently. This includes sifting through, reviewing, and analyzing the millions of documents and several terabytes of data that have been produced to date—a significant and complex undertaking.

This 6(b) inquiry remains one of my top priorities, and I view it as a crucial part of scrutinizing business practices across the pharmaceutical supply chain that can raise drug prices and limit access for patients and that may contribute to the shuttering of independent pharmacies across the country. I share your view that this is a time-sensitive matter of paramount importance, and that we should provide the public and policymakers with as much information about what we are learning and insight about possible competitive harms as quickly as possible. I have asked FTC staff to prioritize doing so to the maximum extent possible, so that dilatory tactics by companies do not prevent us from sharing what we learn in the course of the 6(b) study as quickly as we can. And to be clear: if we find evidence of illegal practices—be it unfair methods of competition or unfair or deceptive practices—I will prioritize bringing the Commission's full authorities to bear.

Separately, I wanted to take the opportunity to ask for your support for two measures essential for a vigorous FTC that can fully protect Americans from unlawful business practices: (1) providing the Commission with the funding necessary for us to fulfill our vital mission; and (2) restoring the Commission's full authority to return money to victimized consumers.[6]

Demands on the Commission continue to grow and strain the agency's resources and capacity as the FTC conducts more 6(b) studies and our merger review and litigation have become more complex, involving cases against some of the most well-resourced companies in the world. While Congress has charged the Commission with a critical mission, our resources have failed to keep pace. We currently employ fewer staffers than we did in the early 1980s, even though our nation's GDP has increased six-fold over the same period, and the Commission has been forced to make difficult decisions about prioritizing investigations. Additional resources would better equip the Commission to fully pursue its mandate and continue the vital work of promoting competition throughout the economy, including in healthcare markets. I look forward to working with Congress to ensure that the Commission has the resources and tools it needs to vigorously protect Americans from unlawful business practices throughout the economy.

With respect to remedies, the Commission's loss of its ability to obtain monetary relief under Section 13(b) has already had a profound effect on consumers and honest businesses: by conservative estimates, this court decision has caused consumers to already lose out on more than $1.5 billion of relief that the agency previously could have obtained under Section 13(b), and the losses increase with each passing day.[7]

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Chair, Federal Trade Commission

UNITED STATES OF AMERICA
Federal Trade Commission
WASHINGTON, D.C. 20580

Office of the Chair

February 13, 2024

The Honorable Cindy Hyde-Smith
United States Senate
Washington, D.C. 20510

Dear Senator Hyde-Smith:

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This can have dire consequences for Americans, with nearly three in ten surveyed Americans reporting rationing or even skipping doses of their prescribed medicines due to high costs.[1] PBMs also have substantial influence over independent pharmacies, which have collectively voiced concern that PBMs impose contractual terms with these pharmacies that are confusing, unfair, arbitrary, and harmful to their businesses.

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Chair, Federal Trade Commission

UNITED STATES OF AMERICA
Federal Trade Commission
WASHINGTON, D.C. 20580

Office of the Chair

February 13, 2024

The Honorable James Lankford
United States Senate
Washington, D.C. 20510

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UNITED STATES OF AMERICA
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Office of the Chair

February 13, 2024

The Honorable Jerry Moran
United States Senate
Washington, D.C. 20510

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This 6(b) inquiry remains one of my top priorities, and I view it as a crucial part of scrutinizing business practices across the pharmaceutical supply chain that can raise drug prices and limit access for patients and that may contribute to the shuttering of independent pharmacies across the country. I share your view that this is a time-sensitive matter of paramount importance, and that we should provide the public and policymakers with as much information about what we are learning and insight about possible competitive harms as quickly as possible. I have asked FTC staff to prioritize doing so to the maximum extent possible, so that dilatory tactics by companies do not prevent us from sharing what we learn in the course of the 6(b) study as quickly as we can. And to be clear: if we find evidence of illegal practices—be it unfair methods of competition or unfair or deceptive practices—I will prioritize bringing the Commission's full authorities to bear.

Separately, I wanted to take the opportunity to ask for your support for two measures essential for a vigorous FTC that can fully protect Americans from unlawful business practices: (1) providing the Commission with the funding necessary for us to fulfill our vital mission; and (2) restoring the Commission's full authority to return money to victimized consumers.[6]

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With respect to remedies, the Commission's loss of its ability to obtain monetary relief under Section 13(b) has already had a profound effect on consumers and honest businesses: by conservative estimates, this court decision has caused consumers to already lose out on more than $1.5 billion of relief that the agency previously could have obtained under Section 13(b), and the losses increase with each passing day.[7]

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Thank you again for your letter and continued leadership on this important issue. If you or your staff have any questions, please don't hesitate to contact Jeanne Bumpus, the Director of the FTC's Office of Congressional Relations, at (202) 326-2195.

Sincerely,

Lina Khan

Lina M. Khan
Chair, Federal Trade Commission

UNITED STATES OF AMERICA
Federal Trade Commission
WASHINGTON, D.C. 20580

Office of the Chair

February 13, 2024

The Honorable Jon Tester
United States Senate
Washington, D.C. 20510

Dear Senator Tester:

Thank you for your January 22, 2024, letter and your continued support of the Federal Trade Commission's (FTC) study of certain pharmacy benefit manager (PBM) industry practices. There is appropriately a high degree of public interest in this industry. The industry's practices and their effects remain opaque despite the central role PBMs play in deciding which drugs are prescribed to patients, which pharmacies patients can use, and how much patients ultimately pay at the pharmacy counter. Decisions by PBMs and their affiliates may have a significant impact on patients' ability to access and afford their prescription drugs.

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Chair, Federal Trade Commission

UNITED STATES OF AMERICA
Federal Trade Commission
WASHINGTON, D.C. 20580

Office of the Chair

February 13, 2024

The Honorable Thom Tillis
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Washington, D.C. 20510

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Chair, Federal Trade Commission

UNITED STATES OF AMERICA
Federal Trade Commission
WASHINGTON, D.C. 20580

Office of the Chair

February 13, 2024

The Honorable Tommy Tuberville
United States Senate
Washington, D.C. 20510

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The PBM 6(b) inquiry seeks to examine several of the most common and serious complaints about PBMs. Our inquiry is aimed at shedding light on several business practices that have drawn public scrutiny in recent years, including: fees and clawbacks charged to unaffiliated pharmacies; methods to steer patients towards PBM-affiliated pharmacies; potentially unfair audits of independent pharmacies; complicated and opaque methods to determine pharmacy reimbursement; the prevalence of prior authorizations and other administrative restrictions; the use of specialty drug lists and surrounding specialty drug policies; and the impact of rebates and fees from drug manufacturers on formulary design and the costs of prescription drugs to payers and patients.

In May and June 2023, the FTC expanded its PBM study by issuing three additional compulsory orders to companies that perform rebate services for their affiliated PBMs.[5] These additional 6(b) Orders require the three group purchasing organizations (GPO) that are linked to the six largest PBMs—Zinc Health Services, LLC, Ascent Health Services, LLC, and Emisar Pharma Services LLC —to produce documents. These GPOs, also called rebate aggregators, negotiate rebates with drug manufacturers on behalf of the PBMs and hold the contracts that govern those rebates. Zinc was founded in 2020 and operates as the GPO for CVS Caremark. Ascent was founded in 2019 and operates as the GPO for Express Scripts, Prime Therapeutics, Envolve Pharmacy Solutions, and Humana Pharmacy Solutions. Emisar, like Zinc and Ascent, negotiates rebates with drug manufacturers. Emisar negotiates rebates on behalf of OptumRx and, like OptumRx, is a subsidiary of UnitedHealth Group.

Although our compulsory orders were issued in June 2022, and May and June 2023, to date no company has turned over sufficient documents and data to be in full compliance with those orders. FTC staff continues to push the PBM/GPOs to finalize their production of documents and data required by the Orders as quickly as possible. The respondents have proceeded with varying levels of speed in their productions and compliance with the Orders. We expect to have all the materials very soon. If, however, some of the companies fail to fully comply with the orders or engage in any actionable delaying tactics, the FTC can take them to court to compel compliance.

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[3] *See* Regulations.gov, Solicitation for Public Comments on the Business Practices of Pharmacy Benefit Managers and Their Impact on Independent Pharmacies and Consumers, FTC-2022-0015 (Feb. 24, 2022), https://www.regulations.gov/docket/FTC-2022-0015. The FTC received 24,100 comments on the Federal Register docket. However, most consist of mass mail campaigns, duplicates, or unrelated comments that are not required to be posted online.

[4] Press Release, Fed. Trade Comm'n, FTC Requests Public Comments on the Impact of Pharmacy Benefit Managers' Practices (Feb. 24, 2022), https://www.ftc.gov/news-events/news/press-releases/2022/02/ftc-requests-public-comments-impact-pharmacy-benefit-managers-practices.

[5] Press Release, Fed. Trade Comm'n, FTC Deepens Inquiry into Prescription Drug Middlemen (May 17, 2023), https://www.ftc.gov/news-events/news/press-releases/2023/05/ftc-deepens-inquiry-prescription-drug-middlemen; Press Release, Fed. Trade Comm'n, FTC Further Expands Inquiry into Prescription Drug Middlemen Industry Practices (June 8, 2023), Launches Inquiry Into Prescription Drug Middlemen Industry (June 7, 2022), https://www.ftc.gov/news-events/news/press-releases/2023/06/ftc-further-expands-inquiry-prescription-drug-middlemen-industry-practices.

Even as FTC staff continues to press the companies to turn over the required documents and data, the team has simultaneously been diligently working through the information and data that we have received, much of it only recently. This includes sifting through, reviewing, and analyzing the millions of documents and several terabytes of data that have been produced to date—a significant and complex undertaking.

This 6(b) inquiry remains one of my top priorities, and I view it as a crucial part of scrutinizing business practices across the pharmaceutical supply chain that can raise drug prices and limit access for patients and that may contribute to the shuttering of independent pharmacies across the country. I share your view that this is a time-sensitive matter of paramount importance, and that we should provide the public and policymakers with as much information about what we are learning and insight about possible competitive harms as quickly as possible. I have asked FTC staff to prioritize doing so to the maximum extent possible, so that dilatory tactics by companies do not prevent us from sharing what we learn in the course of the 6(b) study as quickly as we can. And to be clear: if we find evidence of illegal practices—be it unfair methods of competition or unfair or deceptive practices—I will prioritize bringing the Commission's full authorities to bear.

Separately, I wanted to take the opportunity to ask for your support for two measures essential for a vigorous FTC that can fully protect Americans from unlawful business practices: (1) providing the Commission with the funding necessary for us to fulfill our vital mission; and (2) restoring the Commission's full authority to return money to victimized consumers.[6]

Demands on the Commission continue to grow and strain the agency's resources and capacity as the FTC conducts more 6(b) studies and our merger review and litigation have become more complex, involving cases against some of the most well-resourced companies in the world. While Congress has charged the Commission with a critical mission, our resources have failed to keep pace. We currently employ fewer staffers than we did in the early 1980s, even though our nation's GDP has increased six-fold over the same period, and the Commission has been forced to make difficult decisions about prioritizing investigations. Additional resources would better equip the Commission to fully pursue its mandate and continue the vital work of promoting competition throughout the economy, including in healthcare markets. I look forward to working with Congress to ensure that the Commission has the resources and tools it needs to vigorously protect Americans from unlawful business practices throughout the economy.

With respect to remedies, the Commission's loss of its ability to obtain monetary relief under Section 13(b) has already had a profound effect on consumers and honest businesses: by conservative estimates, this court decision has caused consumers to already lose out on more than $1.5 billion of relief that the agency previously could have obtained under Section 13(b), and the losses increase with each passing day.[7]

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[6] In April 2021 the Supreme Court held that Section 13(b) of the FTC Act does not authorize federal courts to require defendants to pay refunds to harmed consumers or give up the unjust gains they earned from breaking the law. *AMG Capital Mgmt., LLC. v. FTC*, 141 S. Ct. 1341 (2021).

[7] Statement of Commissioner Rebecca Kelly Slaughter Joined by Chair Lina M. Khan Regarding Section 13(b) of the FTC Act (Apr. 28, 2022), https://www.ftc.gov/system/files/ftc_gov/pdf/Statement%20of%20Comm%27r%20Slaughter%20Joined%20by%20Chair%20Khan%20Regarding%20Section%2013%28b%29%20of%20the%20FTC%20Act_April%202022.pdf.

Thank you again for your letter and continued leadership on this important issue. If you or your staff have any questions, please don't hesitate to contact Jeanne Bumpus, the Director of the FTC's Office of Congressional Relations, at (202) 326-2195.

Sincerely,

Lina Khan

Lina M. Khan
Chair, Federal Trade Commission

UNITED STATES OF AMERICA
Federal Trade Commission
WASHINGTON, D.C. 20580

Office of the Chair

February 13, 2024

The Honorable Peter Welch
United States Senate
Washington, D.C. 20510

Dear Senator Welch:

Thank you for your January 22, 2024, letter and your continued support of the Federal Trade Commission's (FTC) study of certain pharmacy benefit manager (PBM) industry practices. There is appropriately a high degree of public interest in this industry. The industry's practices and their effects remain opaque despite the central role PBMs play in deciding which drugs are prescribed to patients, which pharmacies patients can use, and how much patients ultimately pay at the pharmacy counter. Decisions by PBMs and their affiliates may have a significant impact on patients' ability to access and afford their prescription drugs.

This can have dire consequences for Americans, with nearly three in ten surveyed Americans reporting rationing or even skipping doses of their prescribed medicines due to high costs.[1] PBMs also have substantial influence over independent pharmacies, which have collectively voiced concern that PBMs impose contractual terms with these pharmacies that are confusing, unfair, arbitrary, and harmful to their businesses.

Given the importance of this industry and troubling reports about PBM practices, I share your sense of urgency regarding timely completion of the study and welcome this opportunity to provide you an interim progress update on our ongoing study of this industry.

As you know, in June 2022, the FTC issued Orders to PBMs pursuant to its 6(b) authority to study a range of PBM business practices that may affect drug affordability and access.[2] The Order requires the six largest PBMs—Caremark Rx, LLC; Express Scripts, Inc.; OptumRx, Inc.; Humana Pharmacy Solutions, Inc.; Prime Therapeutics LLC; and MedImpact Healthcare Systems, Inc.—to provide data and documents regarding certain business practices. This inquiry

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[1] Ashley Kirzinger, et al, PUBLIC OPINION ON PRESCRIPTION DRUGS AND THEIR PRICES (2023), https://www.kff.org/health-costs/poll-finding/public-opinion-on-prescription-drugs-and-their-prices/; *see also*, Laryssa Mykyta & Robin A. Cohen, *Characteristics of Adults Aged 18–64 Who Did Not Take Medication as Prescribed to Reduce Costs: United States, 2021*, NAT'L CTR. FOR HEALTH STATISTICS (2023) at 5, doi:10.15620/cdc:127680 (research from the CDC found that 9.2 million adults in the U.S. are not taking their prescription drugs as prescribed, due to the high cost of medications).

[2] Press Release, Fed. Trade Comm'n, FTC Launches Inquiry Into Prescription Drug Middlemen Industry (June 7, 2022), https://www.ftc.gov/news-events/news/press-releases/2022/06/ftc-launches-inquiry-prescription-drug-middlemen-industry.

builds on the more than 1,200 public comments[3] the Commission received in response to a request for information about PBMs that the agency issued on February 24, 2022.[4]

The PBM 6(b) inquiry seeks to examine several of the most common and serious complaints about PBMs. Our inquiry is aimed at shedding light on several business practices that have drawn public scrutiny in recent years, including: fees and clawbacks charged to unaffiliated pharmacies; methods to steer patients towards PBM-affiliated pharmacies; potentially unfair audits of independent pharmacies; complicated and opaque methods to determine pharmacy reimbursement; the prevalence of prior authorizations and other administrative restrictions; the use of specialty drug lists and surrounding specialty drug policies; and the impact of rebates and fees from drug manufacturers on formulary design and the costs of prescription drugs to payers and patients.

In May and June 2023, the FTC expanded its PBM study by issuing three additional compulsory orders to companies that perform rebate services for their affiliated PBMs.[5] These additional 6(b) Orders require the three group purchasing organizations (GPO) that are linked to the six largest PBMs—Zinc Health Services, LLC, Ascent Health Services, LLC, and Emisar Pharma Services LLC —to produce documents. These GPOs, also called rebate aggregators, negotiate rebates with drug manufacturers on behalf of the PBMs and hold the contracts that govern those rebates. Zinc was founded in 2020 and operates as the GPO for CVS Caremark. Ascent was founded in 2019 and operates as the GPO for Express Scripts, Prime Therapeutics, Envolve Pharmacy Solutions, and Humana Pharmacy Solutions. Emisar, like Zinc and Ascent, negotiates rebates with drug manufacturers. Emisar negotiates rebates on behalf of OptumRx and, like OptumRx, is a subsidiary of UnitedHealth Group.

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[5] Press Release, Fed. Trade Comm'n, FTC Deepens Inquiry into Prescription Drug Middlemen (May 17, 2023), https://www.ftc.gov/news-events/news/press-releases/2023/05/ftc-deepens-inquiry-prescription-drug-middlemen; Press Release, Fed. Trade Comm'n, FTC Further Expands Inquiry into Prescription Drug Middlemen Industry Practices (June 8, 2023), Launches Inquiry Into Prescription Drug Middlemen Industry (June 7, 2022), https://www.ftc.gov/news-events/news/press-releases/2023/06/ftc-further-expands-inquiry-prescription-drug-middlemen-industry-practices.

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This 6(b) inquiry remains one of my top priorities, and I view it as a crucial part of scrutinizing business practices across the pharmaceutical supply chain that can raise drug prices and limit access for patients and that may contribute to the shuttering of independent pharmacies across the country. I share your view that this is a time-sensitive matter of paramount importance, and that we should provide the public and policymakers with as much information about what we are learning and insight about possible competitive harms as quickly as possible. I have asked FTC staff to prioritize doing so to the maximum extent possible, so that dilatory tactics by companies do not prevent us from sharing what we learn in the course of the 6(b) study as quickly as we can. And to be clear: if we find evidence of illegal practices—be it unfair methods of competition or unfair or deceptive practices—I will prioritize bringing the Commission's full authorities to bear.

Separately, I wanted to take the opportunity to ask for your support for two measures essential for a vigorous FTC that can fully protect Americans from unlawful business practices: (1) providing the Commission with the funding necessary for us to fulfill our vital mission; and (2) restoring the Commission's full authority to return money to victimized consumers.[6]

Demands on the Commission continue to grow and strain the agency's resources and capacity as the FTC conducts more 6(b) studies and our merger review and litigation have become more complex, involving cases against some of the most well-resourced companies in the world. While Congress has charged the Commission with a critical mission, our resources have failed to keep pace. We currently employ fewer staffers than we did in the early 1980s, even though our nation's GDP has increased six-fold over the same period, and the Commission has been forced to make difficult decisions about prioritizing investigations. Additional resources would better equip the Commission to fully pursue its mandate and continue the vital work of promoting competition throughout the economy, including in healthcare markets. I look forward to working with Congress to ensure that the Commission has the resources and tools it needs to vigorously protect Americans from unlawful business practices throughout the economy.

With respect to remedies, the Commission's loss of its ability to obtain monetary relief under Section 13(b) has already had a profound effect on consumers and honest businesses: by conservative estimates, this court decision has caused consumers to already lose out on more than $1.5 billion of relief that the agency previously could have obtained under Section 13(b), and the losses increase with each passing day.[7]

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[6] In April 2021 the Supreme Court held that Section 13(b) of the FTC Act does not authorize federal courts to require defendants to pay refunds to harmed consumers or give up the unjust gains they earned from breaking the law. *AMG Capital Mgmt., LLC. v. FTC*, 141 S. Ct. 1341 (2021).

[7] Statement of Commissioner Rebecca Kelly Slaughter Joined by Chair Lina M. Khan Regarding Section 13(b) of the FTC Act (Apr. 28, 2022), https://www.ftc.gov/system/files/ftc_gov/pdf/Statement%20of%20Comm%27r%20Slaughter%20Joined%20by%20Chair%20Khan%20Regarding%20Section%2013%28b%29%20of%20the%20FTC%20Act_April%202022.pdf.

Thank you again for your letter and continued leadership on this important issue. If you or your staff have any questions, please don't hesitate to contact Jeanne Bumpus, the Director of the FTC's Office of Congressional Relations, at (202) 326-2195.

Sincerely,

Lina Khan

Lina M. Khan
Chair, Federal Trade Commission

United States Senate
WASHINGTON, DC 20510

January 22, 2024

The Honorable Lina Khan
Chair
Federal Trade Commission
600 Pennsylvania Avenue, N.W.
Washington, D.C. 20580

Dear Chair Khan,

We support the Federal Trade Commission's (FTC) issuance of a Section 6(b) order and conducting a timely study of pharmacy benefits managers' (PBM) business practices.[1] You wrote on November 8, 2022, that the FTC's inquiry was "a critical step in more closely scrutinizing business practices across the pharmaceutical supply chain that can raise drug prices, limit access for patients, and contribute to the shuttering of independent pharmacies across the country."[2] With the FTC's inquiry reaching its year-and-a-half mark, we urge the FTC to complete the study without delay. In the interim, we believe it is important to know the status of the study and therefore ask the FTC to issue a progress report.

As you know, PBMs operate with little to no transparency, making it very difficult if not impossible to understand the flow of money in the prescription drug marketplace and how PBMs determine the prices for, and impact the cost of, prescription drugs. Further, recent consolidations between PBMs, insurance providers, and other health care entities have resulted in vertical integration whereby a small number of companies now manage the vast majority of prescription drug benefits. CVS/Caremark, OptumRx, and Express Scripts control roughly 75% of the PBM market and are vertically integrated with insurers Aetna, United Healthcare, and Cigna, respectively.[3] We appreciate the FTC's recent withdrawal of prior advocacy statements and studies that no longer reflect current market realities.[4]

There is widespread bipartisan support for examining PBM practices to determine whether they are causing Americans to pay higher prices for prescription drugs. This support is evident in legislation that has advanced through a number of Senate committees this Congress. The Senate Committee on Commerce, Science, and Transportation advanced S. 127, the Pharmacy Benefit Manager Transparency Act, which would authorize the FTC to hold PBMs

[1] Federal Trade Commission (FTC), "FTC Launches Inquiry Into Prescription Drug Middlemen Industry," June 7, 2022, https://www.ftc.gov/news-events/news/press-releases/2022/06/ftc-launches-inquiry-prescription-drug-middlemen-industry.
[2] Letter from FTC Chair Lina Khan to Senator Charles E. Grassley, November 8, 2022.
[3] U.S. Senate Finance Committee Report, "Insulin: Examining the Factors Driving the Rising Cost of a Century Old Drug," January 14, 2021, https://www.finance.senate.gov/imo/media/doc/Grassley-Wyden%20Insulin%20Report%20(FINAL%201).pdf.
[4] FTC, "FTC Votes to Issue Statement Withdrawing Prior Pharmacy Benefit Manager Advocacy," July 20, 2023, https://www.ftc.gov/news-events/news/press-releases/2023/07/ftc-votes-issue-statement-withdrawing-prior-pharmacy-benefit-manager-advocacy.

accountable for unfair or deceptive practices and add transparency to the PBM market.[5] Another bill, S. 113, the Prescription Pricing for the People Act, was approved by the Senate Judiciary Committee and would direct the FTC to conduct a study and report to Congress within one year on the effects of consolidation and potentially anticompetitive behavior that may impact prescription drug pricing.[6] The Senate Committee on Health, Education, Labor, and Pensions and the Senate Committee on Finance also advanced bipartisan legislation to require more PBM transparency and accountability.

With this bipartisan legislative action taking place, we urge the FTC to complete its 6(b) study in a timely manner. In the interim, we request that you publicly release a progress report on the status of your investigation. A commitment to a timely study and interim progress report will provide transparency, insight about possible competitive harms, and inform the responsiveness and cooperation of impacted parties. We appreciate the FTC's commitment on this matter to patients and taxpayers.

Sincerely,

Charles E. Grassley
United States Senator

Maria Cantwell
United States Senator

James Lankford
United States Senator

Peter Welch
United States Senator

Susan M. Collins
United States Senator

Cindy Hyde-Smith
United States Senator

[5] Pharmacy Benefit Manager Transparency Act, S.127, 118th Cong. (2023), https://www.congress.gov/bill/118th-congress/senate-bill/127.
[6] Prescription Pricing for the People Act, S.113, 118th Cong. (2023). https://www.congress.gov/bill/118th-congress/senate-bill/113.

Christopher A. Coons
United States Senator

Tommy Tuberville
United States Senator

Jerry Moran
United States Senator

Jon Tester
United States Senator

Shelley Moore Capito
United States Senator

Thom Tillis
United States Senator

Mazie K. Hirono
United States Senator

Marsha Blackburn
United States Senator

United States Senate

WASHINGTON, DC 20510

October 6, 2022

The Honorable Lina Khan
Chairwoman
Federal Trade Commissioner
600 Pennsylvania Avenue, N.W.
Washington, D.C. 20580

Dear Chair Khan,

We support the Federal Trade Commission's (FTC) issuance of a Section 6(b) order and conducting a study of pharmacy benefits managers' (PBM) business practices.[1] In your recent participation before the Subcommittee on Competition Policy, Antitrust, and Consumer Rights, you did not commit to a timeline to complete the FTC's PBM study.[2] We believe it is important for this study to be completed in a timely manner as consumers and taxpayers cannot afford any delay. We urge you to publicly commit and for the FTC to complete a study no later than one year from the issuance of the Section 6(b) order.

As you know, PBMs operate with little to no transparency, making it very difficult if not impossible to understand the flow of money in the prescription drug marketplace and how PBMs determine the prices for prescription drugs. Recent consolidations between PBMs, insurance providers, and other health care entities have resulted in vertical integration whereby a small number of companies now manage the vast majority of prescription drug benefits. CVS/Caremark, OptumRx and Express Scripts control roughly 75% of the PBM market and are owned by insurers Aetna, United Healthcare, and Cigna, respectively.

We support legislation that would require the FTC to conduct a study and report to Congress within one year on the effects of consolidation and potentially anticompetitive behavior that may impact prescription drug pricing.[3] A few of the provisions required to be examined in the report include whether PBMs charge certain payers a higher price than competing pharmacies or steer patients to pharmacies at which the PBM has an ownership stake, whether PBMs use formulary designs to depress market share of low cost prescription drugs, and if more information about roles of intermediaries in the healthcare marketplace would benefit consumers. In 2021, this legislation was approved unanimously by the Judiciary Committee and awaits action by the full Senate.

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[1] Federal Trade Commission, "FTC Launches Inquiry Into Prescription Drug Middlemen Industry," June 7, 2022, https://www.ftc.gov/news-events/news/press-releases/2022/06/ftc-launches-inquiry-prescription-drug-middlemen-industry.

[2] Oversight of Federal Enforcement of the Antitrust Laws: hearing before the Subcommittee on Competition Policy, Antitrust, and Consumer Rights, 117th Cong. (2022). https://www.judiciary.senate.gov/meetings/oversight-of-federal-enforcement-of-the-antitrust-laws.

[3] Prescription Pricing for the People Act, S.1388, 117th Cong. (2021). https://www.congress.gov/bill/117th-congress/senate-bill/1388.

There is widespread bipartisan support for examining PBMs and looking into whether they are causing Americans to pay higher prices for prescription drugs. This is why we support the FTC's decision to conduct a PBM study. We hear stories about rising drug costs all the time. A timely study into the business practices of these intermediaries would provide transparency, insight about possible competitive harms, and inform potential legislative action. With the FTC's action on June 7, 2022, there is widespread support for the study and interest to review its findings in a timely manner. To ensure the 6(b) study's usefulness, we urge the FTC to issue the report within one year of its issuance. We appreciate the FTC's commitment on this matter to patients and taxpayers.

Sincerely,

Charles E. Grassley
United States Senator

Maria Cantwell
United States Senator

Cindy Hyde-Smith
United States Senator

James Lankford
United States Senator

Marsha Blackburn
United States Senator

Jerry Moran
United States Senator

Thom Tillis
United States Senator

UNITED STATES OF AMERICA
Federal Trade Commission
WASHINGTON, D.C. 20580

Office of the Chair

June 9, 2022

The Honorable Charles E. Grassley
Ranking Member
Committee on the Judiciary
United States Senate
Washington, D.C. 20510

Dear Ranking Member Grassley:

Thank you for your letter encouraging the Federal Trade Commission ("Commission" or "FTC") to use its investigatory authority under Section 6(b) of the FTC Act to issue orders to pharmacy benefit managers ("PBMs") to study a range of their practices that may affect drug affordability and access.

The Federal Trade Commission this week announced that it will initiate a 6(b) inquiry into the business practices of PBMs.[1] We will require the six largest pharmacy benefit managers—CVS Caremark; Express Scripts, Inc.; OptumRx, Inc.; Humana Inc.; Prime Therapeutics LLC; and MedImpact Healthcare Systems, Inc.—to provide information and records regarding their business practices.

The FTC's PBM inquiry will examine several of the most common complaints about PBMs and will seek to assist policymakers in determining whether Americans would benefit from reforms to this critical industry. Our inquiry is aimed at shedding light on several practices that have drawn scrutiny in recent years, including: fees and clawbacks charged to unaffiliated pharmacies; methods to steer patients towards pharmacy benefit manager-owned pharmacies; potentially unfair audits of independent pharmacies; complicated and opaque methods to determine pharmacy reimbursement; the prevalence of prior authorizations and other administrative restrictions; the use of specialty drug lists and surrounding specialty drug policies; and the impact of rebates and fees from drug manufacturers on formulary design and the costs of prescription drugs to payers and patients.

This inquiry will build on the significant public record developed in response to the request for information about pharmacy benefits managers that the agency launched on February 24, 2022.[2] The agency has received more than 24,000 public comments to date.[3]

I view this inquiry as a critical step in scrutinizing business practices that can raise drug prices and limit access for patients and that may contribute to the shuttering of independent pharmacies across the country. Given that PBMs' practices can have life-and-death consequences for Americans, the FTC has a moral imperative to act with urgency on this vital issue.

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[1] Press Release, Fed. Trade Comm'n., FTC Launches Inquiry Into Prescription Drug Middlemen Industry (June 7, 2022), https://www ftc.gov/news-events/news/press-releases/2022/06/ftc-launches-inquiry-prescription-drug-middlemen-industry.

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[3] *See* Regulations.gov, Solicitation for Public Comments on the Business Practices of Pharmacy Benefit Managers and Their Impact on Independent Pharmacies and Consumers, FTC-2022-0015 (Feb. 24, 2022), https://www.regulations.gov/docket/FTC-2022-0015.

Thank you again for raising this topic. If you or your staff have any questions, please contact Jeanne Bumpus, the Director of the FTC's Office of Congressional Relations, at (202) 326-2195.

Sincerely,

Lina Khan

Lina M. Khan

Chair, Federal Trade Commission

JAMES LANKFORD
OKLAHOMA

316 HART SENATE OFFICE BUILDING
WASHINGTON, DC 20510
(202) 224–5754

United States Senate

COMMITTEES:
FINANCE
ENERGY AND NATURAL RESOURCES
ETHICS
INDIAN AFFAIRS
HOMELAND SECURITY AND GOVERNMENTAL AFFAIRS

June 15, 2022

The Honorable Lina M. Khan
Chairwoman
Federal Trade Commission
600 Pennsylvania Avenue, N.W.
Washington, D.C. 20580

Dear Chair Khan,

I write to you today to thank you for reconsidering the vote that was taken by the Federal Trade Commission (FTC) on February 17, 2022 regarding an investigation into Pharmacy Benefit Manager (PBM) practices. I am thankful the FTC is taking initiative to investigate the pharmaceutical industry and its impact on increasing drug prices through unanimously voting to open an investigation into PBM business practices on June 7, 2022.

Over the last several months, the FTC has heard from hundreds of pharmacies and patients negatively impacted by harmful PBM practices through public comments and open town hall meetings. There is broad consensus in Congress that a plethora of unfair ongoing practices clearly contribute to the inflationary drug prices many Americans face.

I work closely with many Oklahoma pharmacists who have engaged with my office over the last several years to share their frustrations with certain PBM practices such as the issuance of hefty retroactive direct and indirect remuneration (DIR) fees, inconsistent quality metrics, unforeseen contract changes, and an overall lack of clarity. These practices harm patients by artificially increasing drug prices at the pharmacy counter and have led to the closure of independent pharmacies in my state, making it more difficult for rural Americans to access care.

Alarming new data from the Centers for Medicare and Medicaid Services (CMS) show that pharmacy price concessions grew more than 107,400 percent between 2010 and 2020. I have introduced legislation to end this practice and to enforce standardized quality metrics to provide pharmacies clarity and the ability to plan ahead. On April 29, 2022, CMS issued a final rule to require that all pharmacy concessions be passed to the pharmacy counter. While I am thankful for this revolutionary first step, CMS has not been able to address the full scope of the level of control PBMs have on the prescription drug market.

Three PBMs make up about 85% of the market. This margin of control impacts prices, coinsurance levels, and takes away the patient-provider relationship by inserting a powerful, yet greatly unknown, third party.

In 2018, the White House Council of Economic Advisors noted that the PBMs' level of control allows them to "exercise undue market power against manufacturers and against the health plans and beneficiaries they are supposed to be representing, thus generating outsized profits for themselves."[1] It is clear that transparency is needed.

Many PBMs are now a large part of massive conglomerates that include an insurer, a retail pharmacy chain, the PBM that negotiates between plans and drug manufacturers, and now sometimes even physician practices. This ownership structure creates a monopoly over a majority of the health care industry, meaning that the same company is able to decide what drug is prescribed, whether a lower cost generic is available to a patient, what drug is covered by insurance and on what formulary tier it is placed, how much the patient's out-of-pocket requirements are for a drug, and where a patient can access their prescription. This level of integrated control opens the door for anticompetitive practices and incentivizes

[1] Council for Economic Advisors, https://trumpwhitehouse.archives.gov/wp-content/uploads/2017/11/CEA-Rx-White-Paper-Final2.pdf

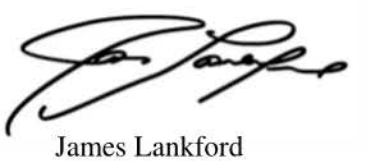
decisions to be made for the benefit of one or all of the several member-companies within an ownership conglomerate, not for the benefit of patients.

PBMs have become one of the most contentious actors in the prescription drug industry. Though their stated goal is to contain costs for the benefit of patients, some PBMs generally benefit from high rebates and exclusive agreements with drug manufacturers. The role rebates play in PBM decision-making not only increases costs but also decreases access to lower cost generic drugs. PBMs are also able to manipulate insurer formularies so that a lower cost drug may actually cost a patient more than a brand drug, based solely on its formulary tier. That does not sound like cost controlling to me; it sounds like patients are suffering and unable to afford their medication while some PBM profit-margins continue to grow.

At the same time Americans are facing record high inflation rates and continued fears about their health after a global pandemic, communities are still losing access to their local pharmacies and paying higher prices for their necessary medications. Patients deserve transparency into business practices impacting their prescription affordability. We should be doing all we can do understand all of the causes of inflated drug prices and pharmacy closures.

I am thankful you were able to build upon existing consensus to come to an agreement with your fellow commissioners on how to properly investigate the prescription drug industry and the role that certain PBM practices play. I look forward to the remaining engaged with the FTC investigation and to shining light on this extremely important issue.

In God We Trust,



James Lankford

United States Senator