



MEMORANDUM

May 18, 2019

To: Subcommittee on Health Democratic Members and Staff

Fr: Committee on Energy and Commerce Democratic Staff

Re: Hearing on “Improving Drug Pricing Transparency and Lowering Prices for American Consumers”

On **Tuesday, May 21, 2019, at 10:30 a.m. in the John D. Dingell Room, 2123 of the Rayburn House Office Building**, the Subcommittee on Health will hold a hearing entitled, “Improving Drug Pricing Transparency and Lowering Prices for American Consumers.”

I. BACKGROUND

Prescription drug spending has increased dramatically in recent years. Retail prescription drug spending in the United States, adjusted for inflation, increased on a per capita basis from \$90 in 1960 to \$1,025 in 2017.¹ In the Medicare program, prescription drugs covered under Medicare Part B and Part D account for nearly 20 percent (\$129 billion) of total Medicare spending, with the majority of that spending occurring in Part D (13 percent).² In 2010, 33,000 Part D enrollees filled a prescription for which a single claim would have been sufficient to meet the Part D out-of-pocket threshold. However, by 2016 that number had jumped to 360,000.³ Independent experts have suggested that greater transparency across the drug supply chain may

¹ Kamal, Rabah, et al, Kaiser Family Foundation “What are the recent and forecasted trends in prescription drug spending?” (2017) (www.healthsystemtracker.org/chart-collection/recent-forecasted-trends-prescription-drug-spending/#item-start).

² For further information on prescription drug coverage in the Medicare program, see: (<https://energycommerce.house.gov/sites/democrats.energycommerce.house.gov/files/documents/Majority%20Memo%20for%20Medicare%20Part%20B%20and%20D%20Drugs%20Hearing%2004.30.19%20%28003%29.pdf>)

³ MedPAC, The Medicare prescription drug program (Part D): Status Report (March 2019) (www.medpac.gov/docs/defaultsource/reports/mar19_medpac_ch14_sec.pdf?sfvrsn=0).

provide insight into why drug prices are continuing to grow and help address the price increases that are leading to higher out of pocket costs for consumers.⁴

II. LEGISLATION

A. **H.R. 2296, Fair Accountability and Innovative Research Drug Pricing Act (the “FAIR Drug Pricing Act”)**

The Medicare Payment Advisory Commission (MedPAC) recently found that nearly all growth in spending among high-cost Part D enrollees between 2007 and 2017 was due to increases in the average price per prescription filled.⁵ A recent analysis has found that prescription drug cost increases are primarily attributable to price increases for drugs already on the market. The cost of brand-name prescription drugs rose more than nine percent a year from 2008 to 2016, and the cost of injectable drugs rose more than 15 percent annually over that same period.⁶

H.R. 2296, the Fair Accountability and Innovative Research Drug Pricing Act or the “FAIR Drug Pricing Act,” sponsored by Reps. Schakowsky (D-IL) and Rooney (R-FL) requires certain drug manufacturers to submit documentation to the Secretary of the Department of Health and Human Services (HHS) 30 days before increasing the price of a qualifying drug. The bill requires manufacturers to report their justification for an increase in the wholesale acquisition cost (WAC) of a qualifying drug should the manufacturer decide to increase the price by 10 percent or more over a 12-month period, or by 25 percent or more over a 36-month period. A manufacturer of a qualifying drug would be required to report the total expenditures for manufacturing the drug, the research and development expenditures for the qualifying drug, and total revenue and net profit generated by the drug, as well as other documentation as applicable. H.R. 2296 would require that the information provided by the manufacturer be published unless it is considered trade secret and confidential. This legislation includes a civil monetary penalty of \$100,000 per day should a manufacturer fail to comply. Annual reports of this information are also required to be provided by HHS to Congress.

B. **H.R. 2069, Stopping the Pharmaceutical Industry from Keeping drugs Expensive Act (the “SPIKE Act”)**

H.R. 2069, Stopping the Pharmaceutical Industry from Keeping drugs Expensive Act, or the “SPIKE Act,” introduced by Reps. Horsford (D-NV) and Reed (R-NY), requires certain drug

⁴ National Academies of Sciences, Engineering, and Medicine, *Making Medicines Affordable: A National Imperative*, (Nov. 2017) (www.nationalacademies.org/hmd/Reports/2017/making-medicines-affordable-a-national-imperative.aspx).

⁵ MedPAC, The Medicare prescription drug program (Part D): Status Report (Mar. 2019) (www.medpac.gov/docs/defaultsource/reports/mar19_medpac_ch14_sec.pdf?sfvrsn=0).

⁶ Inmaculada Hernandez, et al. *The Contribution of New Product Entry Versus Existing Product Inflation in the Rising Costs of Drugs*, Health Affairs (Jan. 2019), (www.healthaffairs.org/doi/abs/10.1377/hlthaff.2018.05147).

manufacturers to submit to the Secretary of HHS documentation justifying: (1) a 10 percent or \$10,000 dollar increase with respect to WAC of any applicable drug over any 12-month period; (2) a 25 percent or \$25,000 dollar increase with respect to WAC over any 36-month period; or (3) a drug that is estimated to cost at least \$26,000 a year or per course of treatment. If the Secretary of HHS determines that a manufacturer's drug product would meet one of these criteria, the manufacturer is required to submit certain information, including total expenditures on research and development, as well as revenue and profit for the applicable drug. A summary of the manufacturer's justification would then be published onto the website of the Centers for Medicare and Medicaid Services (CMS).

C. H.R. 2087, Drug Price Transparency Act

Medicare Part B reimburses health care providers for drugs through a "buy and bill" system, where the provider is responsible for purchasing and storing the drug and may bill Medicare after the drug is administered. The Part B program pays providers 106 percent of the average sales price of a drug (ASP +6 percent). The ASP is calculated by CMS based on a weighted average of sales to all purchasers of a drug nationwide according to quarterly data submitted by the manufacturers.

Current law requires only manufacturers with Medicaid drug rebate agreements to report ASP data to CMS. If a drug lacks ASP data because it is a single-source drug that is new to the market, Medicare will pay WAC plus 3 percent for the first two to three quarters the product is on the market. Some drugs may lack ASP data for reasons other than being new and in these cases the payment method varies and may be 106 percent of WAC, 95 percent of the average wholesale price (AWP), or invoice pricing. Payment based on the WAC or AWP is generally higher than what Medicare would pay under ASP +6, since these alternative payment methods do not incorporate rebates, discounts, and other price concessions. In its June 2017 report to Congress, MedPAC recommended that all manufacturers be required to report ASP data to help ensure the Medicare program is not overpaying for drugs as a result of a lack of ASP data. MedPAC also recommended stronger monetary penalties for failing to report ASP data and additional checks on the quality of data manufacturers report.

H.R. 2087, the Drug Price Transparency Act, introduced by Reps. Doggett (D-TX) and Buchanan (R-FL), requires all manufacturers to report ASP data to CMS for all drugs covered under Medicare Part B, authorizes civil money penalties against manufacturers who fail to report the data or report false data, and improves oversight related to the accuracy of the ASP data reported.

D. H.R. 2115, Public Disclosure of Drug Discounts Act

Pharmacy benefit managers (PBMs) negotiate prices for drugs included on prescription drug formularies, as well as determine what pharmacies will be included in a prescription drug plan's network. PBMs negotiate rebates, discounts, and other fees from manufacturers to develop the plan's formulary and manage prescription drug use and spending on behalf of prescription drug plan sponsors. These negotiated arrangements are proprietary in order to promote competition among competitors. However, there is a lack of transparency in this

confidential industry practice, and therefore it is difficult to understand the impact of this process on drug prices.

H.R. 2115, the Public Disclosure of Drug Discounts Act, sponsored by Reps. Spanberger (D-VA), Arrington (R-TX), and Boyle (D-PA), requires PBMs to disclose the aggregate amount of rebates, discounts, and price concessions that PBMs negotiate with drug manufacturers, and make this information publicly available to allow the public to compare the aggregate rebates, discounts, and price concessions that PBMs receive.

E. H.R. 2376, Prescription Pricing for the People Act of 2019

H.R. 2376, the Prescription Pricing for the People Act of 2019, introduced by Reps. Nadler (D-NY) and Collins (R-GA), would require the Federal Trade Commission (FTC) to conduct a study on the state of competition in the drug supply chain. This study would focus on whether PBMs have engaged in any anti-competitive practices, such as steering patients to pharmacies for anti-competitive purposes, giving such pharmacies more favorable rates than it offers to competing pharmacies, or using its market power to depress the use of lower-cost prescription drugs. The bill also requires that the FTC provide policy recommendations for how to improve transparency and competition in the pharmaceutical supply chain.

F. H.R. 2064, Sunshine for Samples Act of 2019

Section 6002 of the Affordable Care Act (ACA), also known as the Physician Payments Sunshine Act, requires that drug and medical device companies disclose to CMS any payments or other transfers of value made to physicians or teaching hospitals.⁷ This information is published annually and made publicly available and searchable through the Open Payments database.⁸ Companies report on items provided to physicians such as gifts, research, consulting fees, speaking fees, and travel and entertainment expenses. However, Section 6002 excluded the reporting of product samples distributed to physicians.

Section 6004 of the ACA requires that drug manufacturers and distributors report to the Food and Drug Administration (FDA) information on product samples requested and distributed, including information on the specific physician receiving such samples. In 2017, MedPAC recommended that Congress “authorize and require the Secretary to make this information available to researchers, payers, and plans that sign confidentiality and data use agreements” to bring greater transparency to the potential effects of samples on provider prescribing practices.⁹

⁷ See generally Elizabeth Richardson, *The Physician Payments Sunshine Act*, Health Affairs (Oct. 2, 2014) (www.healthaffairs.org/doi/10.1377/hpb20141002.272302/full/) (explaining requirements under the PPSA to report “transfers of value” to CMS).

⁸ Centers for Medicare & Medicaid Services (CMS), Open Payments database (<https://openpaymentsdata.cms.gov/>).

⁹ MedPAC, *Report to the Congress: Medicare and the Health Care Delivery System, Chapter 6* (June 2017) (www.medpac.gov/docs/default-source/reports/jun17_ch6.pdf?sfvrsn=0).

H.R. 2064, the Sunshine for Samples Act of 2019, introduced by Reps. Chu (D-CA) and Nunes (R-CA), would require manufacturers of certain drugs, devices, biologics, or medical supplies to annually report to the Secretary of HHS the total aggregate value and quantity of samples they give to certain health care providers each year. The data would be made publicly available on the Open Payments database beginning in 2023 on an aggregate basis by drug, device, or medical supply, but not by health care provider.

G. H.R. 2757, Creating Lower cost Alternatives for Your prescription drugs Act

Low-income Part D beneficiaries are three times more likely to have to spend such high amounts on drugs so as to cause them to enter the catastrophic phase of the Part D benefit. MedPAC has analyzed that low-income beneficiaries may also be less likely to select available generic drugs.¹⁰ For this reason, MedPAC has recommended modifying copayments for low-income Medicare beneficiaries to encourage the use of generic drugs.¹¹ Similar policies have also been included in both Obama Administration and Trump Administration budget proposals.¹²

H.R. 2757, the Creating Lower cost Alternatives for Your prescription drugs Act, introduced by Reps. Cunningham (D-SC) and Bilirakis (R-FL), eliminates copayment requirements for generic drugs for Part D beneficiaries who receive low-income subsidies (LIS). This bill reduces cost-sharing for generic drugs to \$0 for beneficiaries with income below 150 percent of the poverty line and seeks to incentivize the use of available, higher value products among these beneficiaries.

III. WITNESSES

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¹⁰ See MedPAC, *Report to the Congress: Medicare and the Health Care Delivery System, Chapter 6* (June 2016) (www.medpac.gov/docs/default-source/reports/chapter-6-improving-medicare-part-d-june-2016-report-.pdf).

¹¹ *Id.*

¹² 2020 Budget Fact Sheet, Lowering Drug Prices, *Putting American Patients First: Lowering List Prices, Reducing Out-of-Pocket Costs, and Improving Negotiation and Competition* (www.whitehouse.gov/wp-content/uploads/2019/03/FY20-Fact-Sheet_Lowering-Drug-Pricing-and-Payment_FINAL.pdf).

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