the campaign for
SUSTAINABLE Rx PRICING
Transparency. Competition. Value.

April 5, 2019

The Honorable Alex Azar
Secretary
Department of Health and Human Services
200 Independence Avenue, Southwest
Washington, DC 20201

The Honorable Daniel Levinson
Office of Inspector General
Department of Health and Human Services
330 Independence Avenue, Southwest
Room 5527, Cohen Building
Washington, DC 20201

RE: Fraud and Abuse; Removal of Safe Harbor Protection for Rebates Involving Prescription Pharmaceuticals and Creation of New Safe Harbor Protection for Certain Point-of-Sale Reductions in Price on Prescription Pharmaceuticals and Certain Pharmacy Benefit Manager Service Fees (OIG-0936-P)

Dear Secretary Azar and Inspector General Levinson:

The Campaign for Sustainable Rx Pricing (CSRxP) is a nonpartisan coalition of organizations committed to fostering an informed discussion on sustainable drug pricing and to developing bipartisan, market-based solutions that promote competition, transparency, and value to improve affordability while maintaining patient access to innovative prescription drugs that can improve health outcomes and save lives. Our members represent organizations including consumers, hospitals, physicians, nurses, pharmacists, employers, pharmacy benefit managers and insurance providers.

Prescription drug prices are out of control and continue to grow at unsustainable rates. Twenty-three cents of every health care dollar goes toward prescription drugs.[1] One in four Americans cannot afford their medications. Excessively high prices unfairly threaten the financial security, health and wellbeing of U.S. patients and their families every day, as well as strain Federal and state health budgets and the taxpayers who fund them. Too often patients are faced with the unfortunate and unfair choice of purchasing the medications they need to get well and stay healthy and paying their bills. Patients simply should never be presented with such a choice and deserve affordable access to prescription drugs.

Despite efforts from the brand drug industry to suggest otherwise, brand pharmaceutical companies – and pharmaceutical companies alone – are the drivers of the high drug prices American consumers and taxpayers face every day. Brand manufacturers set unsustainably high launch prices for their products and typically increase those prices at rates that far exceed inflation. A recent AARP study found, for example, that retail prices for 87 percent of the most widely used brand name drugs by older Americans increased from 2016 to 2017, with 30 percent having price increases of 10 percent or higher.[2] Overall, prices for prescription drugs increased by an average of 8.4 percent from 2016 to 2017 – or four times the 2.1 percent rate of general inflation for the period.[3] These 2017 price increases followed

[1] AHIP. "Where Does Your Healthcare Dollar Go?" May 22, 2018.
[2] AARP Public Policy Institute. "Trends in Retail Prices of Brand Name Prescription Drugs Widely Used by Older Americans: 2017 Year-End Update," page 8. September 2018.
[3] *Ibid*., page 5.

average double-digit annual price increases every year from 2012 to 2016.[4] Notably, high-cost specialty medications in particular have been driving unsustainable launch prices and price growth: in 2015, the average annual cost of for a single specialty medication used on a chronic basis exceeded $52,000, with the annual cost of these therapies growing by almost $35,000 from 2006 to 2015.[5]

Given the critical drug pricing crisis facing U.S. consumers and taxpayers today, CSRxP ardently believes it is imperative to rein in the out-of-control drug prices that put patient access to affordable life-saving drugs at risk. We share and applaud the Administration's commitment to lowering drug prices. We agree with the U.S. Department of Health and Human Services (HHS) that the current system can be significantly improved as, in many cases, the system has not adequately addressed the high prices set and controlled entirely by the brand pharmaceutical industry.

That said, however, we strongly oppose the HHS Office of Inspector General's proposed rule (OIG-0936-P) that the Administration purports would reform the system. Rather than reform the system, the proposed rule will lead to the drug industry's imposition of higher – not lower – prices on patients and, perversely, result in raising the profitability of the brand drug industry – the very industry that is responsible for this dire drug pricing problem. [6] Indeed, taking away the ability of health insurance providers and pharmacy benefit managers (PBMs) to bargain with drug makers on behalf of patients will only serve to strengthen drug makers' ability to control the prices they set, weaken insurer and PBM negotiating leverage, and cause higher costs for consumers and taxpayers. And, perhaps of greatest concern, the proposed rule does not address the root cause of the problem: drug makers alone control drug list prices – not insurers and not PBMs – and nothing in this proposed rule prevents brand manufacturers from continuing to engage in abusive price gouging practices that jeopardize patient access to potentially life-saving prescription drugs.

In this vein, CSRxP strongly opposes the HHS OIG's proposed rule entitled "Fraud and Abuse; Removal of Safe Harbor Protection for Rebates Involving Prescription Pharmaceuticals and Creation of New Safe Harbor Protection for Certain Point-of-Sale Reductions in Price on Prescription Pharmaceuticals and Certain Pharmacy Benefit Management Fees." In particular, we wish to underscore that the proposed rule will significantly adversely impact patients, taxpayers, states with Medicaid managed care plans, and the federal government as follows:

1. The commercial bargaining tools employed on behalf of patients by health insurers and PBMs to effectively negotiate lower drug prices with brand drug companies will be removed, giving drug makers even greater ability to impose excessively high prescription drug prices on consumers and taxpayers.
2. Patients will continue to face out-of-control prices for those prescription drugs in particularly without competition because nothing in this proposed rule restricts or limits drug makers' ability to entirely control drug price setting.
3. Premiums will increase substantially – by nearly 20 percent – for all Medicare Part D enrollees, which is especially problematic and concerning for seniors enrolled in Medicare living on limited, fixed incomes.

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[4] *Ibid*., page 6.
[5] AARP. "Trends in Retail Prices of Specialty Prescription Drugs Widely Used by Older Americans, 2006 to 2015," page 1. September 2017.
[6] 84 FR 2356

4. The profitability of the brand drug industry perversely will improve significantly at the expense of taxpayers, Medicare and its beneficiaries.

While the Administration professes to want real reform, this proposed rule falls far short of that standard and harms – rather than helps – patients and taxpayers. As such, we urge HHS to not adopt this proposed rule and instead develop bipartisan, market-based solutions that improve prescription drug affordability while at the same time foster innovation and preserve access to medically necessary therapies. CSRxP would welcome the opportunity to continue our discussions with HHS on policy alternatives that would inject more commercial negotiating tools and competition into the marketplace to lower prescription drug costs for consumers and taxpayers.

1. No Impact on Brand Drug Makers' Ability to Entirely Control Price Setting Coupled with Significantly Weakened Negotiating Leverage from Health Insurers and PBMs on Behalf of Patients

Contrary to the claims of the Administration and brand drug industry, health insurance providers and PBMs are not simply "middlemen" in the drug supply chain. Rather, health insurers and PBMs play critical roles in bargaining on the behalf of patients to lower the high prices that brand drug makers impose on patients. The rebates, price concessions, and other discounts negotiated by health insurers and PBMs on behalf of patients significantly reduce prescription drugs costs for consumers and taxpayers. Without the negotiating power and collective bargaining leverage of the PBMs and health insurers, manufacturers would set even higher prices and patient access to affordable medications would be at even greater risk. Simply put, despite the contention of the brand drug industry, health insurers and PBMs are not responsible for high list prices; rather, drug manufacturers solely are responsible and should be held accountable for their unfair pricing practices that harm patients. Drug makers set high list prices and PBMs and insurers effectively use their commercial negotiating tools to bring those unnecessarily high prices down for patients.

Indeed, recent research definitively concluded that there is no correlation between the prices drug companies set and the rebates they negotiate with PBMs and, importantly, that drug companies increase prices regardless of rebate levels. [7] The study found prominent cases of higher-than-average price increases in drug categories where manufacturers negotiated relatively low rebates and, conversely, prominent cases of lower-than-average price increases in drug categories where manufacturers negotiate relatively high rebates.[8] In other words, clear evidence demonstrates that rebates negotiated by PBMs do not correlate with or necessarily lead to higher list prices – rather drug makers entirely set and control high list prices imposed on consumers and taxpayers.

In fact, rebates and other discounts negotiated by PBMs and Medicare Part D plans produce significant savings for Medicare, its beneficiaries, and taxpayers – nearly $90 billion in savings since the inception of the program in 2006 to 2016 and a projected $300 billion in savings from 2017 to 2026, according to one recent analysis. [9] The Medicare Trustees confirmed this analysis, projecting in

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[7] Visante. "No Correlation between Increasing Drug Prices and Manufacturer Rebates in Major Drug Categories." April 2017.
[8] *Ibid*.
[9] Milliman. "Value of Direct and Indirect Remuneration: Impact on Part D Prescription Drug Plan (PDP) Stakeholders." July 2017.

their most recent report significantly slower growth in Part D spending in part due to higher manufacturer rebates negotiated by PBMs.[10]

Given the clear evidence of the value that PBMs and health insurers provide in lowering prescription drug costs, CSRxP strongly opposes the proposed rule because it will remove the ability of PBMs and health insurers to negotiate with drug makers, adversely impacting Medicare Part D, Medicare beneficiaries, states with Medicaid managed care plans and taxpayers. Rather than take away the leverage health insurers and PBMs deploy in negotiating with drug manufacturers, HHS instead should be extending even greater flexibility to these critical players in the drug supply chain to negotiate even lower prescription drug costs for patients.

2. No Changes to Brand Drug Maker Price Gouging Practices for High-Priced Drugs without Competition

Everyone agrees that prescription drugs without competition– often high-cost specialty biologic products – pose especially significant cost challenges for federal health programs like Medicare and the U.S. healthcare system more broadly both now and in the future. The HHS Assistant Secretary for Planning and Evaluation (ASPE) found, for example, that Medicare Part B spending on prescription drugs increased at a rapid average annual rate of 7.7 percent from 2005 to 2014; during that period, specialty biologic medicines (often without significant competition) grew at a particularly fast rate, climbing from 39 percent to 62 percent of total spending, with a substantial share of the growth due to price increases rather than number of patients using the medications.[11] Separately, a large PBM recently found that its clients' spending on specialty medications increased 9.4 percent while spending on traditional, non-specialty medications decreased 5.8 percent in 2017.[12]

Humira, the best-selling pharmaceutical product in the world today with nearly $20 billion in sales in 2018, illustrates the critical problem posed by high-priced medications without competition. Humira has over 100 patents that potentially could extend its market protection as far as 2034 in the U.S., but likely at least through 2022.[13] [14] [15] [16] As a result of the anti-competitive and unfair patent "thicket" and "pay-for-delay" deals reached between the manufacturers of Humira and its biosimilars, U.S. patients taking Humira needlessly will continue paying a high price for this drug for at least the next three years and likely will face significant price increases throughout this time.

It is of critical concern, therefore, that pricing reforms tackle drugs with limited or no competition. Unfortunately, however, the changes to the system in this proposed rule do nothing to address this critical problem. Rather, under the proposed rule, manufacturers retain complete control in price

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[10] The Board of Trustees, Federal Hospital Insurance and Federal Supplementary Insurance Trust Funds. "2018 Annual Report of the Board of Trustees of the Federal Hospital Insurance and Federal Supplementary Insurance Trust Funds," page 112.
[11] HHS Assistant Secretary for Planning and Evaluation. "Medicare Part B Drugs: Pricing and Incentives," page 6. March 8, 2016.
[12] Express Scripts. "2018 Drug Trend Report."
[13] Gonzalez, Richard. "Abbvie Long-Term Strategy." October 30, 2015. Slides 14 - 16.
[14] Pollack, Andrew. "Makers of Humira and Enbrel Using New Drug Patents to Delay Generic Versions." The New York Times. July 15, 2016.
[15] Slide presentation by Michael Carrier at FTC November 8, 2017 workshop. Slide 48.
[16] AbbVie. "AbbVie Reports Full-Year and Fourth-Quarter 2018 Financial Results." January 25, 2019.

setting and have increased leverage over health insurers and PBMs that no longer can use commercial negotiating tools to lower costs for patients and taxpayers. Instead of weakening the bargaining powers of the health insurers and PBMs on behalf of patients, CSRxP urges HHS to not adopt the proposed rule and instead take steps to increase such powers so that brand drug makers actually feel pressure to lower prescription drug prices for patients.

3. Significant Premium Increases for All Medicare Part D Enrollees

CSRxP lauds the Department's overarching goal to reduce prescription drug costs for patients. Hence, we do not understand why HHS seeks to implement policies in this proposed rule that will raise – not lower – prescription drug costs for patients. Indeed, all Medicare Part D enrollees will face substantial premium increases of nearly 20 percent per month as a result of this proposed rule, according to the Department's Office of the Actuary.[17] Clearly, significantly raising premiums for all Part D beneficiaries will not make prescription drug coverage more affordable and will be particularly problematic for the many Medicare beneficiaries who live on fixed incomes and simply cannot afford unnecessary increases to their monthly Part D premiums.

In fact, since the inception of the Part D program, rebates and other discounts negotiated by PBMs and health insurers have saved Part D beneficiaries an estimated 21.5 percent on their premiums – or more than $12 billion savings.[18] Assuming HHS does not implement this proposed rule, health insurer and PBM bargaining tools are projected to save beneficiaries 33.2 percent on premiums – or nearly $50 billion – from 2017 through 2026.[19]

CSRxP firmly believes that patients should continue to benefit from the significant premium savings that PBMs and health insurers have negotiated on their behalf. Therefore, rather than diminishing the leverage that PBMs and health insurers hold over drug manufacturers, we urge HHS to consider market-based alternatives that will make prescription drugs more – not less – affordable for patients. Clearly raising Part D premiums through implementation of this proposed rule would not advance this very important goal and we thus urge HHS to not adopt the proposed rule.

4. Improving the Profitability of the Pharmaceutical Industry at the Expense of Taxpayers, Medicare Beneficiaries, and Medicare

CSRxP is extremely concerned that brand drug makers' profitability will significantly improve bottom at the substantial expense of taxpayers and federal health programs as a result of this proposed rule. One estimate projects brand drug makers will pay out nearly $40 billion less in price discounts in the Part D coverage gap over 2020 – 2029 as a result of the proposed rule.[20] In other words, the bottom lines of the brand drug industry will improve as a result of a the proposed changes in this rule, which the Administration purports is seeking to address the very serious drug pricing problem facing all Americans today that the industry itself solely caused. Moreover, at the same time, the HHS Office of the Actuary projects that Medicare Part D spending will increase by more than $196 billion over 10 years if this rule

[17] 84 FR 2358
[18] Milliman. "Value of Direct and Indirect Remuneration: Impact on Part D Prescription Drug Plan (PDP) Stakeholders." July 2017.
[19] *Ibid*.
[20] 84 FR 2362

is implemented.[21] This enormous increase in Medicare Part D spending hurts beneficiaries and taxpayers, making the program substantially less financially stable for its enrollees and the taxpayers who fund it.

Put another way, taxpayers and Medicare beneficiaries perversely will pay out nearly $200 billion to subsidize the profitability of the brand drug industry – the very industry responsible for the drug pricing problem – if HHS implements this rule. To be very clear, implementation of this proposed rule wrongly and inappropriately will: (1) put Medicare on less sound financial footing for current and future beneficiaries, which is particularly problematic for those seniors on limited, fixed incomes who depend on the program to provide them health security as they age; and (2) require taxpayers and Medicare beneficiaries to pad the bottom lines of the brand pharmaceutical industry – a perverse and adverse outcome that will financially benefit the very industry that has caused the drug pricing problem that this proposed rule ostensibly seeks to address. CSRxP therefore urges on behalf of Medicare beneficiaries and taxpayers that HHS not adopt this proposed rule and instead consider bipartisan, market-based alternatives that will increase competition and lower prescription drug prices for consumers.

Conclusion

In conclusion, CSRxP again wishes to express appreciation for the HHS's clear commitment to lowering prescription drug prices for all Americans and the actions taken by the Department to date to advance this critical policy goal. Unfortunately, however, this proposed rule will have the opposite effect: rather than improving prescription drug affordability, this proposed rule takes away the very tools that health insurers and PBMs leverage in negotiations with drug makers to lower costs for patients and, as a result, further jeopardizes patient access to affordable prescription drugs – all at the expense of taxpayers who perversely would have to fund higher profits for the drug industry. Most importantly, this proposed rule does nothing to address the root cause of the problem: brand drug companies alone – and brand drug companies alone – set list prices way too high and raise those prices at unsustainably high rates.

CSRxP firmly believes that without major actions by HHS and others, the brand pharmaceutical industry will continue to excessively profit from their unfair and unsustainable pricing practices that increase drugs costs and jeopardize access for the patients who need them. CSRxP looks forward to working with HHS to develop alternative bipartisan, market-based policies that promote transparency, foster competition, and incentivize value to improve affordability for consumers while at the same time maintaining access to the treatments that can improve health outcomes and save lives.

Sincerely,

Lauren Aronson
Executive Director
The Campaign for Sustainable Rx Pricing

[21] 84 FR 2359