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Department of Health & Human Services
200 Independence Ave, SW
Room 600E
Washington, D.C. 20201

Comments of Consumers Union, U.S. PIRG,
Consumer Action and Coalition to Protect Patients Choice

HHS Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs
RIN: 0991-ZA49

The undersigned stakeholders, representing consumer organizations who are concerned about the high cost of prescription medications, submit these comments in the above-referenced proceeding. We applaud the U.S. Department of Health & Human Services ("HHS") for taking the initiative to release its "Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs" ("Blueprint") and soliciting comments from the public that will help shape the agency's future policy development and action.

With the Blueprint, HHS has taken what could be important first steps toward actually bringing down and controlling the escalating costs of prescription drugs. These rapidly increasing costs threaten our nation's ability to control the cost of healthcare overall. The unreasonably high out-of-pocket cost for prescription drugs threatens patients' access to medicines, as some may choose to stop or delay treatment because they cannot afford it. Ensuring that patients can afford life-saving and life-managing prescription drugs is critically important to the public health of the nation, because it will increase usage of necessary medications that help patients live longer and healthier lives. Accordingly, the Administration's efforts to contain drug costs are appreciated.

The Blueprint has identified four goals to lower drug costs for consumers: increase competition, negotiate better, create incentives for lowering list prices, and reducing out-of-pocket spending. As set forth more fully below, we believe that competition would be increased through streamlining approval of generic and biosimilar medicines, and by increasing transparency in the pricing of drugs throughout the supply chain; that better negotiations could be promoted by examining the incentives and conflicts of interests of pharmacy benefit managers ("PBMs"), and by considering elimination of the PBM rebate system; and that supporting adoption of generic and biosimilar medicines, as well as changing the PBMs incentives, would help both lower list prices and reduce out-of-pocket costs.

The practices and negotiating tactics of PBMs, along with lack of competition and lack of transparency, are a key structural component to the escalating list prices and increasing out-of-pocket costs for consumers. We urge HHS to consider eliminating rebates and pharmacy gag rules, imposing fiduciary duty on PBMs, and more broadly increasing supply chain transparency. "American patients," HHS points out, "have the right to know what their prescription drugs will

really cost before they get to the pharmacy."[1] Accordingly, we support Secretary Azar's proposal to "fundamentally ... re-examine the role of pharmacy benefit managers."[2]

Besides reining in PBMs, we urge HHS to consider eliminating "gag clauses" that prevent pharmacists from telling customers how they can sometimes save on prescriptions by paying in cash, and to stop pharmaceutical companies from engaging in anticompetitive schemes to game the regulatory approval process to delay the entry of lower-cost generic drugs.[3]

Problems in the PBM Market Raise Costs and Drug Prices for Consumers.

Although PBMs offer the potential to control pharmaceutical costs, there has been a pattern of conflicts of interest, self-dealing and anticompetitive conduct, all of which ultimately means that consumers pay more for the drugs they need than they should. After a comprehensive study, the White House Council of Economic Advisers found that the three large PBMs control more than 85% of the market, "which allows them to exercise undue market power against manufacturers and against health plans and beneficiaries they are supposed to be representing, thus generating outsized profits for themselves."[4] Indeed, PBMs make larger profits than any other players involved in the drug supply chain (distributors, insurers, or pharmacies).[5] PBMs take advantage of a lack of transparency, misaligned incentives, and conflicts of interest. Ultimately this leads to higher drug costs.[6]

PBM Consolidation and Integration Harms Competition

We affirm the Administration's focus on the benefits of increasing transparency and decreasing concentration in the PBM industry. Transparency is necessary for consumers to evaluate products carefully, to make informed choices, and to secure the full range of services they desire. The PBM market lacks the essential elements for a competitive market: (1) transparency, (2) choice and (3) a lack of conflicts of interest.[7] The lack of enforcement, regulation, and competition has created a situation in which PBMs reign free to engage in anticompetitive and deceptive conduct that harms consumers, employers, unions, and pharmacists.[8] The profits of the major PBMs are increasing at

[1] Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs, Request for Information, U.S. Department of Health & Human Services ("HHS"), May 14, 2018.
[2] Secretary Alex Azar Interview on CNBC's Squawk Box, May 11, 2018 at https://www.cnbc.com/2018/05/11/azar-says-everybody-is-wetting-their-beak-on-high-drug-list-prices.html.
[3] *See 6 Ways Trump's Drug Price Plan Could Lower Rx Costs,* Lisa L. Gill, Consumer Reports, May 11, 2018, https://www.consumerreports.org/drug-prices/ways-trumps-drug-plan-could-lower-rx-costs/.
[4] Reforming Biopharmaceutical Pricing at Home and Abroad, The Council of Economic Advisors, White Paper, February 2018.
[5] *Hidden Profits in the Prescription Drug Supply Chain*, Charlie Grant, February 24, 2018, Wall Street Journal.
[6] *Id.*
[7] *"Protecting Consumers and Promoting Health Insurance Competition,"* Testimony of David Balto, Before House Judiciary Committee, Subcommittee on Courts and Competition Policy, October 8, 2009 at http://www.dcantitrustlaw.com/assets/content/documents/CAP/protecting%20consumers.pdf .
[8] *How PBMs Make Drug Pricing Problem Worse*, David Balto, August 31, 2016, The Hill; *The State of Competition in the Pharmacy Benefits Manager and Pharmacy Marketplaces*, Hearing before Subcomm. on Regulatory Reform, Commercial and Antitrust Law, House Comm. on the Judiciary, November 17, 2015 (statement for record of Lynn

a rapid pace, and now exceed $6 billion annually.[9] PBMs are not adequately fulfilling their function in controlling costs – indeed, PBM profits are increasing at the same time drug costs increase, in part because PBMs secure higher rebates from the increased prices charged. Plan sponsors (employers and unions) cannot attack this problem, because PBMs fail to provide adequate transparency, and because of the lack of competition.

Currently, three PBMs (CVS Caremark, Express Scripts, and UnitedHealth's OptumRx) control 85% of their tier in the drug supply chain.[10] OptumRx is already vertically integrated in common ownership with a health insurer. Two pending vertical mergers between PBMs and insurers (CVS/Aetna and Express Scripts/Cigna) would further exacerbate the concerns associated with an already concentrated and anticompetitive PBM market. PBMs must be free of conflicts of interest that arise from common ownership with their own pharmacies or their own health insurer. What health plans and employers are fundamentally wanting to purchase when they contract with a PBM is the services of an "honest broker" to secure the lowest prices and best services from both pharmaceutical manufacturers and from pharmacies. When the PBM is commonly owned with the entity it is supposed to bargain with, or has its own mail order operations, there is an inherent conflict of interest, which can lead to deception, anticompetitive conduct, and higher prices.

The three major PBMs clearly face this conflict, since they own mail order operations, specialty pharmacies, and, in the case of CVS Caremark, the largest retail and specialty pharmacy chain and the dominant long-term care pharmacy. If the two pending mergers referenced above are permitted, all three major PBMs would own their own health insurer as well. While vertical mergers do not directly eliminate rivals, they enhance the ability and incentive for the merged firm to behave in ways that harm competition and consumers. In the PBM context, there are already problems with conflicts of interest and a lack of transparency, and those concerns would be exacerbated by these mergers.[11] Without independent health insurers to question the costs, there's no one to police the PBM rebate scheme or to make sure rebate savings are shared with consumers. Maintaining independent entities in the drug supply chain allows for more scrutiny over pricing.

Quincy and George P. Slover, Consumers Union), https://consumersunion.org/research/the-state-of-competition-in-the-pharmacy-benefits-manager-and-pharmacy-marketplaces/.

[9] Reforming Biopharmaceutical Pricing at Home and Abroad," The Council of Economic Advisors, White Paper, February 2018.

[10] Testimony of David Balto Before the California Senate Committee on Business Practices and Economic Development, March 20, 2017 at http://www.dcantitrustlaw.com/assets/content/documents/testimony/PBM%20Testimony.Balto.pdf .

[11] That is why the leading consumer competition advocacy association opposes these mergers. *See* Letter from Diana Moss, President of American Antitrust Institute, to Assistant Attorney General of the Antitrust Division, Makan Delrahim, March 26, 2018; *Why the DOJ Must Block the Cigna-Express Merger*, David Balto, The Hill, March 27, 2018; *CVS-Aetna Merger is a Robber Baron's Dream Come True*, David Balto, The Hill, December 6, 2017; testimony of George Slover, Consumers Union, Competition in the Pharmaceutical Supply Chain: The Proposed Merger of CVS Health and Aetna, Hearing before Subcomm. on Regulatory Reform, Commercial and Antitrust Law, House Comm. on the Judiciary, Feb. 27, 2018, https://judiciary.house.gov/wp-content/uploads/2018/02/Slover-Testimony.pdf.

That's why we are urging the Justice Department to thoroughly investigate these mergers, and to oppose them outright if the concerns we see are borne out. That would be the most effective way of preventing the increased harm to competition and consumers.

Skewed PBM Incentives Lead to Increased List Prices

As Secretary Azar has highlighted, the PBM rebate system exacerbates the conflicts of interest, which leads to inflating the list prices of prescription drugs, ultimately making consumers pay more.[12] The role of the PBM has evolved over time, and increasingly PBMs are able to "play the spread" by not properly sharing the savings they secure in under-the-table rebates from drug manufacturers. (The rebates are effectively under the table, since the PBMs refuse to disclose information about the amount of the rebates). PBMs earn enormous profits by negotiating rebates and discounts with drug manufacturers in exchange for promoting certain drugs on their preferred formulary, or for engaging in drug substitution programs. PBMs also negotiate contracts with pharmacies to determine how much the pharmacists will be paid for dispensing medication and providing services.

By paying a lower reimbursement rate to pharmacies, while failing to adequately disclose reimbursement rates and manufacturer rebates, PBMs generate substantial hidden profits. In both respects, PBMs can play the spread by failing to disclose these forms of indirect compensation. Keeping the size of these rebates hidden denies purchasers important information that impacts their buying decisions. As a result, this lack of information often results in higher costs for consumers, health plans, employers, and other plan sponsors.

Rebates also create an inherent and perverse incentive for PBMs to actually support higher drug list prices, because that can make room for higher rebates. Generally, the more expensive the list price of the drug, the higher the rebate the PBM can obtain – and often there are higher co-pays as well.[13] That is a big part of the reason rebates have been increasing over the past several years. And because the market is not competitive or transparent, those rebates or kickbacks are increasingly pocketed by the PBMs, and health plans and consumers have few means of either policing or escaping from the resulting higher costs.

In fact, PBM profits have skyrocketed over the past 15 years. Since 2003, the two largest PBMs – Express Scripts and CVS – have seen their profits increased by almost 600%, from $900 million to nearly $6 billion.[14] It's no surprise that rebates have more than doubled, to over $153 million, in the last five years.[15] How much of these rebates and other discounts to PBMs were actually passed on to consumers? What we do know is that consumers' out-of-pocket costs went up. Eliminating rebates would dismantle the incentive structure that has perversely encouraged PBMs to negotiate for higher list prices and to choose medications that are more expensive to consumers.

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[12] Secretary Alex Azar Interview on CNBC's Squawk Box, May 11, 2018 at https://www.cnbc.com/2018/05/11/azar-says-everybody-is-wetting-their-beak-on-high-drug-list-prices.html.
[13] *Id.*
[14] *See, e.g.*, David Balto, *How PBMs Make the Drug Price Problem Worse*, The Hill (August 31, 2016).
[15] *The Gross to Net Bubble Topped $150 billion in 2017*, Adam J. Fein, Drug Channels, April 24, 2018 at https://www.drugchannels.net/2018/04/the-gross-to-net-rebate-bubble-topped.html.

PBMs do not currently have to answer to anyone. They are essentially unregulated, and contend that they have no fiduciary duty to the health plans and employer customers on whose behalf they are supposedly negotiating. To ensure that the PBM is fulfilling the interests of its customers, the Administration should make clear that PBMs owe a fiduciary duty to the entities for which they are managing pharmaceutical benefits.

Reducing Patient Out-of-Pocket Spending by Eliminating Gag Clauses

We also welcome HHS's efforts to eliminate pharmacy gag clauses that prevent pharmacists from informing consumers of lower priced alternatives. In a competitive market we would expect providers would have the ability to guide consumers to the best products at the lowest cost. The fact that PBMs can prevent pharmacies from disclosing this information demonstrates their market power and a clear market failure. In the absence of competition working as it should, regulation is necessary to ensure that consumers are protected.

As consumers face rising prescription drug costs, HHS should prohibit PBMs from inserting provisions in their contracts with pharmacists that keep pharmacists from telling consumers about lower cost alternatives or that the cash price for a prescription drug may be less expensive than their insurance co-pay. In other words, the gag clause prevents a pharmacist from voluntarily telling a customer about lower cost alternatives or that she could save money by paying cash for a prescription drug rather than using her health insurance. The only purpose of the gag clause is to conceal the costs of prescription drugs from consumers at the pharmacy, causing consumers to pay more, with the only clear benefit going to the PBM's bottom line.

Unfortunately, most consumers are not provided with a full set of information when purchasing a prescription drug. It is not obvious to a consumer that sometimes the cheapest way to buy prescription drugs at the pharmacy is to pay cash rather than to use her insurance plan. When those situations arise, a pharmacist should be allowed to do the right thing so consumers can make an informed purchase and save money.

Secretary Azar is right to call out gag clauses as "unacceptable" and to work with Congress on legislation prohibiting PBMs from requiring, implementing, and enforcing gag clauses, because consumers have a right to know the costs of their prescription drugs. However, HHS should not wait for legislation; it should take action immediately where it can, starting with Medicare and Medicaid, as gag clauses serve no procompetitive purpose and their elimination would be an important step towards increasing drug pricing transparency for consumers.

Stop Brand Pharmaceutical Companies From Gaming the FDA Review and Approval Process to Block Competition

Finally, we also support efforts to promote generic and biosimilar competition. Generic competition saves consumers billions of dollars every year. Currently, the U.S. Food and Drug Administration ("FDA") approves potentially dangerous drugs under Risk Evaluation and Mitigation Strategies ("REMS") programs when a drug's benefits outweigh its risks. Under FDA rules, generic companies need access to brand samples to conduct drug product development and

bioequivalence studies necessary for FDA approval. But certain pharmaceutical companies have misused the FDA safety rules imposed in connection with FDA-mandated REMS, to forestall competition by refusing to supply manufacturers samples needed to develop more affordable generic alternatives and satisfy FDA approval requirements. In other words, branded drug manufacturers will refuse to sell samples to generic firms under the guise of safety, but with the real purpose of maintaining their monopolies. These access delays due to REMS abuse cost patients and taxpayers more than $5 billion each year, and put needed medication out of reach for millions of consumers.[16]

These abuses are examples of how the regulatory process can be misused as a tool to delay effective competition.[17] One of the most pernicious ways for a company to acquire or maintain market power in a regulated market can be through abuse of government processes.[18] The cost to the company engaging in such abuse typically is minimal, while the anticompetitive harms resulting from such abuse often are significant.[19] Anticompetitive conduct through regulatory process abuse can be especially pernicious. When one company acquires and enjoys a leading position in the marketplace, we can normally expect other companies to rise up and compete against it. But abuse of the regulatory process blocks these natural competitive forces in ways that are very difficult to overcome. That is especially the case in the pharmaceutical industry, where regulatory approval is a necessary condition for market entry.

The Federal Trade Commission has indicated that a brand-name drug maker's refusal to sell samples to potential generic rivals could be an antitrust violation.[20] Meanwhile, FDA Commissioner Scott Gottlieb is making it a top priority to stop drug manufacturers from gaming the patent system to block generic competitors. In his words, drug makers must "end the shenanigans" that prevent competing products from reaching the market.[21] HHS Secretary Azar has stated that "it's time to shed light on these practices and call out the manufacturers who may be abusing the rules that built our free market for drugs. They're using laws intended to promote the public health to pad their profits instead."[22]

Despite clear statements from Congress, the FDA, and Secretary Azar that drug firms should not abuse REMS programs to block or delay generic or biosimilar competition, [23] complaints about

[16]Lost Prescription Drug Savings from the Use of REMS Programs to Delay Market Entry, Alex Brill, MatrixGlobal Advisors, July 2014.
[17] *Removing Obstacles to Generic Drug Competition*, Center for American Progress, David Balto, June 23, 2009, at 20.
[18] *Id.*
[19] *Id.*
[20] Prepared Statement of Federal Trade Commission, Before the United States House of Representatives Judiciary Committee Subcommittee on Regulatory Reform, Commercial and Antitrust Law on "Antitrust Concerns and the FDA Approval Process" Washington, D.C., July 27, 2017.
[21] Drug Company Shenanigans Come Under Federal Scrutiny," New York Times, April 14, 2018.
[22] Remarks on Drug Pricing Blueprint, Alex M. Azar II, HHS, May 14, 2018.
[23] Prepared Statement of FTC, at 7 citing to FDAAA subsection f(8) states that no holder of a REMS-covered drug shall use an aspect of the REMS to "block or delay approval" of an ANDA. 21 U.S.C. § 355-1(f)(8) and Center for Drug Evaluation and Research, FDA, Risk Evaluation and Mitigation Strategy (REMS) Public Meeting (July 28, 2010), at 270-71 (statement by Jane Axelrad, Associate Director of Policy, Center for Drug Evaluation and Research), http://www.fda.gov/downloads/Drugs/NewsEvents/UCM224950.pdf; FDA, Risk Evaluation and

abuse of the regulatory process persist. Indeed, in May, FDA Commissioner Gottlieb noted that there have been 164 reports of generic drug makers requesting assistance from the FDA because of these delay tactics.[24] The FDA also published two draft guidance documents to help ensure generic drug makers get through the development and approval processes more efficiently for drugs that have heightened safety requirements.[25]

We applaud the FDA's efforts to call out the abusers by publishing names of brand companies that refuse to provide reference product samples to generic manufacturers, and to establish a more efficient process for generic drug approval, but more is required.

We encourage the Administration to ensure that lower-priced generic and biosimilar medicines are able to launch at the earliest possible date, without being blocked by abusive patent or regulatory gamesmanship. To do this effectively, the Administration needs to step up its efforts to make sure that the CREATES Act, bipartisan legislation explicitly prohibiting companies from using restricted access programs as a way to block generic competition, is passed. The legislation is projected to save American taxpayers $3.8 billion over 10 years through savings to Medicare and Medicaid, and would result in billions in additional savings for American consumers.[26] The Administration should review existing REMS programs to determine whether distribution restrictions are even appropriate; expand generics' access to samples necessary for generic development; and take steps to facilitate generics' access to products that are under distribution limitations by the manufacturers. Addressing the loophole that invites the abuses will encourage generic drug competition, and generate billions of dollars in savings for consumers.

The Administration should also prevent other patent abuse tactics employed by some pharmaceutical companies. The Federal Trade Commission should investigate and challenge the use of sham regulatory filings and other efforts to subvert the regulatory process. Patent gamesmanship is an enormous problem that drives up prescription drug cost to patients and consumers. One of the key ways to stem these abuses is to maintain a strong *inter partes* review process at the Patent and Trademark Office.

Mitigation Strategies; Notice of Public Meeting; Reopening of Comment Period, 75 Fed. Reg. 34453, at 34456 (June 17, 2010) (noting FDAAA subsection f(8) and requesting input on steps FDA could take "to ensure that REMS are not used to block or delay generic competition").

[24] Creates Act Will Bring Lower Priced Prescription Drugs to Market for Hardworking Americans, David N. Cicilline (D-R.I.) and Tom Marino (R-PA.), The Hill, July 3, 2018.

[25] *Id.*

[26] Drug Company Shenanigans Come Under Federal Scrutiny, Robert Pear, NY Times, April 14, 2018.

Conclusion

We encourage the Administration to continue its efforts to reduce prescription drug prices for all consumers. If you have further questions, please feel free to contact David Balto at david.balto@dcantitrustlaw.com.

Respectfully submitted,

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David Balto on behalf of Coalition to Protect Patients Choice