Center for Medicare Advocacy

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The Honorable Ron Wyden
Ranking Member, Committee on Finance
United States Senate
Washington, D.C. 20510

The Honorable Charles Grassley
Senior Member, Committee on Finance
United States Senate
Washington, D.C. 20510

Submitted electronically to: Report_Feedback@finance.senate.gov

Re: Comments on Prescription Drug Pricing Reform

Dear Ranking Member Wyden and Senior Member Grassley:

The Center for Medicare Advocacy (Center) is pleased to provide the Senate Finance Committee comments in response to the January 21, 2016 request for feedback on reforming prescription drug pricing policy. The Center, founded in 1986, is a national, non-partisan education and advocacy organization that works to ensure fair access to Medicare and to quality health care. At the Center, we educate older people and people with disabilities to help secure fair access to necessary health care services. We draw upon our direct experience with thousands of individuals to educate policy makers about how their decisions affect the lives of real people. Additionally, we provide legal representation to ensure that people receive the health care benefits to which they are legally entitled, and to the quality health care they need.

We are grateful that the Committee has taken the time to address this issue and bring greater attention to the problem through "The Price of Sovaldi and its Impact on the U.S. Health Care System." We applaud the bipartisan efforts of Ranking Member Wyden and Senior Member Grassley to seek guidance on potential platforms for legislative reform. Although the Committee's focus in this endeavor is currently centered on reforming the market surrounding breakthrough and single-source innovator drugs, the issue of drug pricing does extend beyond just single-source drugs and merits discussion here as well.

Overall, we agree with the Committee that the prioritization of revenue and profit maximization within the pharmaceutical industry, at the risk of worsening patient access, is a cause for concern. We also agree with the Committee that Congress must address policy issues regarding "the financial impact of high prices of breakthrough drugs, ensuring patient access, and improving marketplace transparency." Given that Medicare beneficiaries are severely impacted by the rising cost of prescription drugs, the health care needs of older adults and people with disabilities should be at the center of these efforts.

As articulated in the January 21st request for comments, the Committee has identified five questions that need to be addressed for the development of bipartisan legislation. These include the following: (1) what role does the concept of "value" play in this debate, and how should an innovative therapy's value be represented in its price? And (2) what tools exists, or should exist, to address the impact of high cost drugs and corresponding access restrictions, particularly on low-income populations and state Medicaid programs? We have organized our comments, below, around these two questions. As you consider and draft policy, we ask that you consider our following principles and stated goals.

I. What role does the concept of "value" play in this debate, and how should an innovative therapy's value be represented in its price?

The concept of value must be paired with the need for patient access. Nevertheless, patient access adds little value when the prescription drug is equally or less effective than competing drugs and higher in cost. Adopting policy relating to the use of cost-effectiveness research could open access to information that would allow for measuring a prescription drug's value, factoring in effectiveness and price, in the treatment of illnesses. In this context, we also believe a greater examination should be undertaken to ensure that the price of a breakthrough prescription drug is not being arbitrarily inflated based on market exclusivity rather than the value that a drug actually brings to a patient's treatment. Lastly, we endorse policy that interprets the value of prescription drugs without factoring in marketing costs.

A. Implementing Cost-Effectiveness Research

Cost-effectiveness research involves the evaluation of different treatment options for a given illness and the subsequent measurement of each option's impact on a group of patients.[1] Cost-effectiveness research can have immediate results within the prescription drug market, as evidenced by Zaltrap.[2] Zaltrap is a colon cancer drug that cost $11,000 a month when it first reached the market; however, Memorial Sloan-Kettering Cancer Center in New York soon after determined that use of the drug was unfeasible because it was twice as expensive as a similar drug while producing no greater effectiveness in combatting the illness.[3] Consequently, the manufacturer cut the cost of Zaltrap by half.[4]

While cost-effectiveness research provides an avenue for determining whether a new breakthrough drug actually does provide value to a patient's treatment, the U.S. currently

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[1] Congressional Budget Office, *Research on the Comparative Effectiveness of Medical Treatments: Issues and Options for an Expanded Federal Role* 3 (2007), available at https://www.cbo.gov/sites/default/files/110th-congress-2007-2008/reports/12-18-comparativeeffectiveness.pdf.

[2] Andrew Pollack, *Sanofi Halves Price of Cancer Drug Zaltrap After Sloan-Kettering Rejection*, N.Y. Times (Nov. 8, 2012), available at http://www.nytimes.com/2012/11/09/business/sanofi-halves-price-of-drug-after-sloan-kettering-balks-at-paying-it.html?_r=0.

[3] *Id.*

[4] *Id.*

lacks comprehensive and publicly available cost-effectiveness research.[5] In a study comparing the impact of cost-effectiveness research on oncology drugs approved between 2000 and 2011 in the U.S. and Europe, the study pointed out that "the average price of the drugs in Europe was 10 percent lower than the average US average wholesale price and 8 percent lower than the average US average sale price and [Medicare] Part D price."[6] Additionally, the study highlighted that, between 2000 and 2011, the U.S. Food and Drug Administration approved 41 oncology drugs whereas the European Medicines Agency only approved 31 of the same class of drugs.[7]

According to a report by The Commonwealth Fund, the lack of cost-effectiveness research "makes it difficult for clinicians, other decision-makers, and patients to make informed choices on which interventions work best and under what circumstances."[8] As a result, the Obama administration has already offered encouragement and support in adopting cost-effectiveness research, alongside the support of clinicians, insurers, patients, and other advocacy groups.[9]

- For more information on cost-effectiveness research, see: https://www.cbo.gov/sites/default/files/110th-congress-2007-2008/reports/12-18-comparativeeffectiveness.pdf.

B. Analyzing the Role of Market Exclusivity and Transparency

While market exclusivity may drive innovation, it can also inflate the value of a given prescription drug. One policy option would be to allow market exclusivity to be awarded in a limited amount of circumstances and, primarily, as an award to pharmaceutical companies that substantially improve patient treatment; pharmaceutical companies should not be rewarded exclusivity for simply meeting FDA standards by producing safe and effective medication.[10] There must be a greater examination of the role market exclusivity plays in determining the value of a breakthrough prescription drug in comparison to the value it offers patients in treatment.

For example, the breakthrough of Sovaldi in treating the Hepatitis C Virus (HCV) ensured market exclusivity in the U.S. until a competitor drug was brought to the

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[5] Joshua Cohen et al., *Compared To US Practice, Evidence-Based Reviews In Europe Appear To Lead To Lower Prices For Some Drugs*, 32 Health Affairs 762 (2013). (highlighting that some critics have argued cost-effectiveness research will obstruct patient access and pharmaceutical innovation, while proponents have argued it as a rational approach to address the unsustainable rise in prescription drug pricing).
[6] *Id.* at 765.
[7] *See id.* (presenting that the U.S. was also first in approving the marketing of 29 drugs).
[8] Corinna Sorenson, The Commonwealth Fund, *Use of Comparative Effectiveness Research in Drug Coverage and Pricing Decisions: A Six-Country Comparison* (July 2010), available at http://www.commonwealthfund.org/~/media/Files/Publications/Issue%20Brief/2010/Jul/1420_Sorenson_Comp_Effect_intl_ib_71.pdf (arguing that the U.S. should adopt policy addressing cost-effectiveness research).
[9] *Id.* at 1.
[10] *See* AARP et al., Letter to Senators Lamar Alexander and Richard Burr (Feb. 23, 2015) (offering the points stated here in a comment to the Senators' "Innovation for Healthier Americans" white paper).

market.[11] Accordingly, Gilead Sciences had the opportunity to increase the price of Sovaldi from the $36,000 for a 12-week treatment to $84,000 after it acquired the drug's original developer.[12] In neighboring Canada, the same course of treatment cost nearly $34,000 less. While in India, Gilead Sciences even licensed the drug to seven Indian manufactures for the production of cheaper, generic forms of the drug.[13] The disparity in cost between the U.S. prescription drug market and foreign markets only propel further questions about what role value plays in prescription drug pricing.

Ultimately, no evidence suggests that expanding market exclusivity will actually result in greater innovation. Yet, the evidence does point out that current incentives tend to favor market potential and profit; in the last decade, approved prescription drugs largely consisted of minor variations of existing drugs and showed no greater effectiveness in clinical measures.[14] As a result, any action to build on existing incentives should be done with extreme caution.

Greater examination of market exclusivity and incentives for innovation can be aided by greater transparency of the development costs of prescription drugs. With pharmaceutical companies pointing to research and development costs as the driver of prescription drug prices, increasing transparency will allow consumers to have a better understanding of the reasoning behind a given drug's pricing. Consequently, better informed clinicians, providers, health care advocates, and patients will then be in a position to exert pressure on pharmaceutical companies to lower prescription drug prices when justified.

Although we strongly support promoting the development of innovative treatments, the reward of market exclusivity demands greater scrutiny and focus as to what value a drug actually has in treating patients. In this aim, we urge the adoption of tools that increase the transparency of prescription drugs. Greater transparency will not only help answer questions regarding the role that value plays in prescription pricing but, also, will lead to more informed consumers.

C. Factoring out Marketing Costs

Marketing costs do not add any value to the impact that a prescription drug has on the treatment of an illness. Accordingly, we support policy that interprets the value of prescription drugs without factoring in marketing costs. One report that looked at 16 of the top 30 prescription drugs in 2014 found that all but one pharmaceutical company spent exponentially more on marketing than on research and development.[15] Moreover, the report also determined that all the pharmaceutical companies, including the one

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[11] *The Price of Sovaldi and its Impact on the U.S. Health Care System*, S. Prt. 114-20, at 1 (2015).
[12] *Id.* at 2.
[13] *Id.* at 58.
[14] See Joshua J. Gagne & Niteesh K. Choudhry, *How Many 'Me-Too' Drugs Is Too Many?* 305 JAMA 7 (2011) 711, 712; M. Lanthier, et al., *An Improved Approach To Measuring Drug Innovation Finds Steady Rates Of First-In-Class Pharmaceuticals, 1987 -2011*," 32 Health Affairs 8 (2013), 1433-1439.
[15] Erik Sherman, *The real reason U.S. drug prices are so high*, CBS News (Oct. 7, 2015), http://www.cbsnews.com/news/higher-drug-prices-support-profits-not-research/.

company with higher research and development costs, still saw after-tax profits in the billions of dollars.[16]

Pharmaceutical companies often emphasize the cost of research and development as the cause for rising prescription drug prices. Yet, studies, like the one above, have already demonstrated that the bulk of pharmaceutical expenditures stem from marketing costs. In fact, another study has also shown that pharmaceutical companies spent more than $27 billion on marketing alone in 2012.[17] In other words, the industry spends two to nineteen times more on marketing than on research and development.[18] As a result, we support initiatives that remove the high cost of marketing from any calculations of what value a given prescription drug has and offers patients.

II. What tools exists, or should exist, to address the impact of high cost drugs and corresponding access restrictions, particularly on low-income populations and state Medicaid programs?

In the section below, we strongly urge Congress to restore Medicare drug rebates. Half of all Medicare beneficiaries lived on incomes of $24,150, or less, in 2014.[19] Nevertheless, Medicare beneficiaries spent an average of $4,722 on out-of-pocket costs in 2012.[20] By restoring the Medicare drug rebate, Congress will not only help lower the nation's deficit but will also provide cost-saving measures for Medicare beneficiaries in critical need of such measures. For this reason, Congress should also grant the Secretary of the Department of Health and Human Services the authority to negotiate drug prices as a means of reducing the effect of high cost drugs. Finally, we urge Congress to allow the government the ability to leverage federal funds used in the research and development of prescription drugs to curb rising prices.

A. Restoring Medicare Drug Rebates

While the passage of the Medicare Modernization Act (MMA) has allowed millions of older adults and people with disabilities to gain access to prescription drug coverage, the MMA has also severely limited the government's ability to control drug prices within the Medicare program. The Medicare program has seen the rebates offered by

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[16] *Id.*

[17] *Persuading the Prescribers: Pharmaceutical Industry Marketing and its Influence on Physicians and Patients*, The Pew Charitable Trusts (Nov. 11, 2013), http://www.pewtrusts.org/en/research-and-analysis/fact-sheets/2013/11/11/persuading-the-prescribers-pharmaceutical-industry-marketing-and-its-influence-on-physicians-and-patients

[18] Senator Jay Rockefeller, *Medicare Drug Savings and Pharmaceutical Research & Development (R & D)* (Apr. 2013), available at http://www.medicareadvocacy.org/wp-content/uploads/2013/11/FS-Part-D-Rebates-and-Research-and-Development.pdf.

[19] *See* Gretchen Jacobson et al., *Income and Assets of Medicare Beneficiaries, 2014 – 2030*, Kaiser Family Foundation (Sept. 10, 2015), http://kff.org/medicare/issue-brief/income-and-assets-of-medicare-beneficiaries-2014-2030/ (clarifying that the 25% of beneficiaries has incomes below $14,350).

[20] *See* Juliette Cubanski et al., *Health Care on a Budget: The Financial Burden of Health Spending by Medicare Households*, Kaiser Family Foundation (Jan. 09, 2014), http://kff.org/medicare/issue-brief/health-care-on-a-budget-the-financial-burden-of-health-spending-by-medicare-households/ (highlighting that "Health expenses accounted for 14% of Medicare household budgets in 2012").

pharmaceutical companies decrease and their costs increase. Consequently, President Obama, in the administration's 2017 budget proposal, once again advocated for the restoration of Medicare drug rebates.

In 2011, a report by the House Committee on Oversight and Government Reform determined that the cost of the top 100 drugs for dually eligible beneficiaries was 30% higher under Medicare than it would have been under Medicaid.[21] Likewise, a 2012 analysis by the Department of Health and Human Services (DHHS) Office of Inspector General compared the prices of 200 brand name drugs under Medicaid and Medicare Part D reached similar conclusions. The study found that the Medicaid rebates required by law reduced expenditures by 47% for the drugs under review. In comparison, Part D rebates secured through negotiations with private plans reduced expenditures by only 15%.[22] In total, the Congressional Budget Office (CBO) estimates that restoring Medicaid-level drug rebates for low-income Medicare beneficiaries could save an estimated $141.2 billion over ten years.[23]

We strongly urge Congress to restore Medicare prescription drug rebates. Medicaid rebates have already proven to be successful in lowering drug prices and increasing government savings. Restoring Medicare rebates is a reasonable solution to growing costs and leaves little uncertainty in determining its effectiveness.

- For more information on restoring Medicare drug rebates, see: http://www.lcao.org/files/2013/02/LCAO-Drug-Rebates-Issue-Brief-Jan2013.pdf.

B. Allowing the Secretary of the Department of Health and Human Services to Negotiate Medicare Drug Prices

The Medicare Modernization Act of 2003 grants private Medicare Part D plan sponsors the authority to negotiate prescription drugs prices with pharmaceutical companies. However, Congress added a noninterference clause that bars the government from taking part in negotiations, as it does under Medicaid.[24] We urge Congress to delegate to the HHS Secretary the authority to negotiate drug prices with pharmaceutical companies. The

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[21] *67 House Members Urge Boehner to Include Medicare Drug Price Negotiation in Final Debt Reduction Deal*, Letter to Speaker Boehner from Rep. Hinchey, Rep. Schakowsky, Rep. Sam Barr and Rep. Peter Welch (June 2011), available at http://www.democratunity.com/about-joomla/site/68-issues/economy/3068-67-house-members-urge-speaker-boehner-to-include-medicare-drug-price-negotiation-in-final-debt-reduction-deal-; Building on What Works: Restoring Medicare Drug Rebates, Leadership Council of Aging Organizations, http://www.lcao.org/files/2013/02/LCAO-Drug-Rebates-Issue-Brief-Jan2013.pdf (offering the information presented here in greater detail).

[22] Office of the Inspector General, *Medicaid Rebates for Brand-Name Drugs Exceeded Part D Rebates by a Substantial Margin*, Dep't of Health and Human Servs. (Apr. 2015).

[23] Office of Senator Jay Rockefeller, *Press Release: Rockefeller and 18 Other Senators Introduce Legislation to Protect Seniors & Reduce the Deficit by $141.2 Billion* (Apr. 2013), available at: http://www.rockefeller.senate.gov/public/index.cfm/press-releases?ID=617fffeb-4c5a-4123-a5b3-1f8b790e5f8b.

[24] Juliette Cubanski & Tricia Neuman, *Searching for Savings in Medicare Drug Price Negotiations*, Kaiser Family Foundation (Feb. 09, 2016), http://kff.org/medicare/issue-brief/searching-for-savings-in-medicare-drug-price-negotiations/.

Congressional Budget Office (CBO) reported that, in general, a reduction in cost might be realized if the Secretary had the authority to negotiate prices.[25] Nevertheless, a 2008 CBO report added that a greater amount of savings could be realized in negotiating the cost breakthrough drugs without competitors in the market.[26] We also urge Congress to adopt legislative solutions, such as the Medicare Drug Savings Act, which, at the very least, would allow low-income Medicare Part D beneficiaries to access drugs at the same price offered to Medicaid beneficiaries.

- For more information on granting the HHS Secretary the authority to negotiate drug prices, see: http://www.ncpssm.org/PublicPolicy/Medicare/Documents/ArticleID/1138/Issue-Brief-Medicare-Drug-Negotiation-and-Rebates.

C. Leveraging Government Subsidized Research and Development

Pharmaceutical companies often receive federal funding for researching and developing new prescription drugs. In combination with allowing the HSS Secretary the authority to negotiate Medicare drug prices, the government should be allowed to leverage federally funded research and development to lower prescription drug prices. It is unreasonable to allow pharmaceutical companies to receive taxpayer funds for the research and development of their drugs and, at the same time, allow them to price the public out of seeking treatment through the use of those drugs.

Pharmaceutical companies currently operate in a more than generous and favorable environment due to federally funded research, tax breaks, and patent legislation.[27] In fact, one study has already shown that, in 2013, the federal government provided nearly 27% of all direct research and development funding in the U.S.[28] Although those in the pharmaceutical industry might claim that high prescription drug prices are still legitimate despite government incentives because of the total weight of research and development costs, the reality is that the industry expends anywhere between two to nineteen times more on marketing.[29]

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[25] Congressional Budget Office, Letter to the Honorable Ron Wyden (Mar. 3, 2004), available at https://www.cbo.gov/sites/default/files/108th-congress-2003-2004/reports/03-03-wyden.pdf; see also *See Policy Options to Sustain Medicare For the Future*, Kaiser Family Foundation 50 (Jan. 2013), available at https://kaiserfamilyfoundation.files.wordpress.com/2013/02/8402.pdf ("CBO based the lack of scored savings on the premise that the HHS Secretary would have no leverage for negotiation in the absence of any power to require a formulary and thus to obtain discounts in recognition of preferred formulary status.").

[26] *See Policy Options to Sustain Medicare For the Future*, *supra* note 25 (providing that the HHS Secretary could lower costs through the power of persuasion or "requiring plans to use prior authorization for specified drugs for which no discount is provided as part of a negotiation strategy").

[27] Senator Jay Rockefeller, *Medicare Drug Savings and Pharmaceutical Research & Development (R & D)* (Apr. 2013), available at http://www.medicareadvocacy.org/wp-content/uploads/2013/11/FS-Part-D-Rebates-and-Research-and-Development.pdf.

[28] Mark Boroush, *U.S. R&D Increased in 2013, Well Ahead of the Pace of Gross Domestic Product*, Nat'l Ctr. for Sci. and Eng'g Statistics (Sept. 2015), available at http://www.nsf.gov/statistics/2015/nsf15330/nsf15330.pdf.

[29] *See supra* note 27.

- For more information on federally funded pharmaceutical research and development, see: http://www.medicareadvocacy.org/wp-content/uploads/2013/11/FS-Part-D-Rebates-and-Research-and-Development.pdf.

Conclusion

Once again, we thank Ranking Member Wyden and Senior Member Grassley for bringing further attention to the issue of prescription drug prices. We also appreciate the opportunity to provide feedback on possible legislative reforms to combat the rising cost of prescription drugs. Above all, we urge Congress to place the needs of Medicare beneficiaries, for the reasons discussed above, at the forefront of any reform efforts.

Sincerely,

David Lipschutz
Kata Kertesz
Dara Valanejad
Center for Medicare Advocacy