COUNCIL FOR AFFORDABLE
HEALTH COVERAGE

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March 4, 2016

The Honorable Ron Wyden
Ranking Member
Committee on Finance
219 Dirksen Senate Office Building
Washington, D.C. 20510

The Honorable Charles Grassley
Member
Committee on Finance
219 Dirksen Senate Office Building
Washington, D.C. 20510

RE: Request for Information on Policy Issues Including the Financial Impact of High Prices of Breakthrough Drugs, Ensuring Patient Access, and Improving Marketplace Transparency

Submitted Electronically

Dear Ranking Member Wyden and Senator Grassley,

The Council for Affordable Health Coverage (CAHC) is pleased to comment on your Request for Information on Policy Issues Including the Financial Impact of High Prices of Breakthrough Drugs, Ensuring Patient Access, and Improving Marketplace Transparency, issued on January 21, 2016.

CAHC is a broad-based alliance with a singular focus: bringing down the cost of health care for all Americans. Our membership represents a broad range of interests – organizations representing small and large employers, manufacturers, retailers, insurers, patient groups, and physician organizations. Our full membership list is available on our website at www.cahc.net.

We believe there are significant government barriers to lowering drug costs and that implementing reforms to several existing policies and programs will help to not only lower costs, but also improve outcomes for patients through value-based contracting arrangements. We have identified some of these barriers and solutions in this letter. CAHC is working on a more comprehensive drug cost reform proposal that we will share with you and your staff in the coming weeks.

CAHC's comments reflect the positions of the Council, but may not necessarily reflect the individual views of our members.

1) **Address Research and Development Costs to Drive Down Consumer Prices**
   (Question #5)

Many considerations factor into the pricing of biopharmaceutical products, spanning issues from the cost of research and development through the cost of biologics production to coverage and compliance with post-approval regulatory requirements. It is important to understand the various issues that contribute to the cost of products as you consider any next policy steps.

A 2014 report published by the Tufts Center for the Study of Drug Development (CSDD) has identified the average cost of developing a prescription drug that achieves market approval at $2.6 billion, an increase of 145 percent from 2003. Increased clinical trial complexity, larger clinical trial sizes, increased costs of running a clinical trial generally, and increased demand by Medicare and other payers for comparative effectiveness data and other post-market clinical trial requirements were significant factors

contributing to this cost increase. While lengthier development and approval times were not cited by the study as contributing factors to increasing costs, we know from interviews with manufacturers that these factors do, in fact, increase costs.

We encourage you to focus on reforms to streamline pre-market research and development requirements as ways to lower costs while maintaining appropriate safety and quality standards. Further, as payers, including Medicare, increasingly demand post-market trials and additional data that increase costs, we urge a thorough review of the value this process brings to the market. Among other areas, reforms might include:

- Creating efficiencies and reciprocity among trial testing sites to help reduce unnecessary administrative expenditures that increase drug sticker price.

- Identifying the costs and necessity of conducting separate coverage trials for Food and Drug Administration (FDA)-approved products, and identifying where efficiencies can be brought to bear, without lowering the bar for drug approval standards, to reduce costs when such trials are necessary.

- Increasingly using standardized inclusion, exclusion, data formats, and standards to help encourage administrative and operational efficiencies.

- Requiring regular review of the FDA's progress in using innovative health information technology (health IT) to model the effects of drugs and biologics in humans and to characterize molecular details of new products. Successful utilization of health IT can further streamline the drug research and review process, thereby enabling greater cost efficiencies.

2) Support Competition for Breakthrough Drugs to Reduce Systemic Health Costs *(Question #1)*

New single source medications that offer breakthrough improvements to current medical treatment options provide significant therapeutic advances for patients and medical providers, helping to cure diseases or turn fatal illnesses into chronic conditions.

In the short-term, these types of drugs tend to enter the market at a higher initial price point and contribute to an increase in prescription drug spending. Pricing decisions reflect numerous factors, including therapeutic area competition, economics, utilization and volume, coverage, and government policy. Whether the increase in prescription drug spending lowers overall health care spending and for how long is highly dependent on the individual factors related to specific drug products. Recent examples show these advances can generally lead to overall lower systemic costs for the health care system.[i] This is largely because patient adherence to new breakthrough drugs has cascading positive impacts, helping to reduce transplantation, hospitalizations, physician office visits, avoidable hospital admissions, and emergency room visits.[ii] Depending on the innovation, new breakthrough drugs can also motivate systemic delivery change through the creation of efficiencies in treatment that allow for the reallocation of health care resources to other areas in need.[iii]

In addition, competition around new, innovative breakthrough drugs plays a crucial role in helping to reduce prices and contribute to lower total health care costs. Payers and pharmacy benefit managers

(PBMs) leverage competition to negotiate lower prices through discounts and rebates that significantly reduce the net prices of breakthrough drugs, particularly when new competitor products enter the market. For these trends to continue, we need to ensure that there is strong support for innovation and competition among prescription drugs and other therapies both now and in the future.

For example, the HCV medications featured in your report provide an appropriate case study illustrating this cycle and the importance of competition for breakthrough drugs.

- An estimated 3.2 million Americans are living with chronic Hepatitis C (HCV) infection, with approximately 17,000 new cases each year.[iv] Without effective treatment, HCV can lead to very serious complications that may require advanced and costly medical care, while substantially reducing patients' quality of life. In 2014, Milliman estimated the average billed charges for 30 days pre- and 180 days-post liver transplant to be $739,100.[v]

- Previous treatments cured roughly half of patients with HCV and tended to have unpleasant and dangerous side effects—including depression, irritability, flu-like symptoms, anemia, heart disease, and heart attack.[vi,vii,viii]

- In contrast, new HCV treatments, including Sovaldi, Harvoni, and Viekira Pak, achieve cure rates upwards of 90 percent and offer minimal side effects.[ix,x,xi] We estimate these treatments added 4.6 percentage points to the growth in prescription drug spending in 2014. This reflected a temporary increase, because as more products entered the market, significant pricing constraint and negotiations around rebates and discounts fueled lower cost growth, adding 0.6 percentage points to the growth of prescription drug spending in 2015.

- For 2016 and beyond, prescription drug spending towards HCV treatments is expected to remain level and ultimately decrease in the long-term as the medications continue to reduce the prevalence of HCV by approximately 120,000 per year.[xii]

- At the same time, we have generally not seen the type of continued pricing increases some were concerned about with the release of new competing HCV treatments. In fact, what we have seen are competitive discounting, prior authorization, and other utilization controls including formulary exclusions, leading to big price concessions up to almost half of the list price for these products. As market competition increased in 2015, PBMs obtained nearly half-price discounts for new HCV treatments, with average rebates increasing from about 22 percent in 2014 to 46 percent in 2015.[xiii,xiv,xv,xvi,xvii] We view these trends, fostered by innovation and competition around breakthrough drugs, as a positive development.

Many patient groups hope for these types of innovations. At the same time, we must be able to afford these advances. We urge you to pursue reforms to support and enhance the continued innovation of breakthrough drugs, while promoting a competitive marketplace that fosters aggressive incentives for private payers to negotiate discounts and other cost concessions.

3) **Avoid Policies That Create Barriers to Lower Cost Prescription Drugs in Medicare** *(Question #5)*

Medicare Part D has set the standard for delivering better value at a lower cost. As such, CAHC is extremely concerned about any proposal that would undermine the fundamental structure of this program. Unfortunately, some recently-proposed reforms to the system would do just that. For instance, imposing Medicaid-style rebates and interfering in plan, pharmacy, and manufacturer negotiations would likely lead to higher costs in the system. Attempts to divest part of negotiation power and increasing taxes on manufacturers, plans, or beneficiaries is, in our opinion, the wrong prescription.

Instead, we urge you to focus on market-based solutions to lower the cost of prescription drugs and to exploit opportunities to integrate pharmacy and medical benefits as is possible under Medicare Advantage. Rebates lead to lower net costs for plans, employers, pharmacy benefit managers, and other purchasers; but mandatory rebates shift costs in the system to other parts of the system – e.g., from Medicaid market channels to commercial market channels. In this case drug manufacturers are challenged to recoup the full costs of the drug development process and its fixed costs and its failures, by pricing products in a manner that covers a hidden subsidy from the commercial market to government programs. Therefore, the CBO expects that requiring Medicaid-style rebates in Part D would likely cause higher prices for other beneficiaries in Medicare Part D and reduce incentives for drug manufacturers to develop new drugs, eroding potential savings in the long-term.[xviii] Partly as a result, mandatory rebates will increase premiums by 20 to 40 percent, according to the American Action Forum.[xix]

In addition, repealing non-interference will not save money unless Congress is willing to grant the Department of Health and Human Services (HHS) power to set a national formulary, and indirectly sanction limiting access to drugs or pharmacies. As shown by the Veterans Affairs formulary, a government set formulary would drastically reduce patient access to medicines.

Medicare Part D and Medicare Advantage should be protected as an example of how competition and consumer choice can work in a restructured Medicare program for all beneficiaries. Encouraging strong competition provided by health plans who are working diligently to keep costs down, attract beneficiaries, and negotiate for savings can be leveraged program-wide.

As you seek to address any problems associated with drug pricing, we strongly urge you to abandon "solutions" that will only lead to new or worsened problems by, first, doing no harm to the highly successful Medicare Part D program.

4) **Facilitate Value-Based Arrangements to Improve Outcomes and Lower Costs** *(Question #3)*

The overall health system is undergoing a monumental shift as it rapidly moves toward paying for value. Bundled payments, accountable care, evidence-based medicine, and value-based insurance design have become key themes in the transition away from the volume-based fee-for-service system to a results-based system. Yet, the discussion and policy decisions surrounding value have not focused on the role prescription drugs can play in reformed reimbursement models even as these new medicines reshape the treatment landscape and disrupt old ways of dealing with disease. The debate thus far also has generally focused exclusively on cost rather than patient value and health outcomes.

We urge you to consider the barriers that stand in the way of value based payment arrangements for biopharmaceutical products. Under a value-based payment arrangement, payers and pharmaceutical companies would increase the link between payment (a rough proxy for price) for a medicine to the value and medical outcomes achieved, much as several commercial and Medicare models already do for hospitals and physicians.

We believe these arrangements would encourage the use of high-value prescription drugs over those with less proven clinical value. To the extent such arrangements become more common, it would encourage biopharmaceutical manufacturers to focus their drug development programs more on data for patient outcomes, satisfaction rates, and overall effectiveness of a product during the drug development phase. Ultimately, this type of payment arrangement would encourage more resources to be allocated to medicines that provide the most benefit to patients at the lowest cost to payers and society.

Key policy approaches that should be factored into policy considerations concerning value-based arrangements are outlined below.

Reform Rules Concerning Communication Between Manufacturers and Payers to Better Price for Value

Health plans begin pricing plan premiums and designing benefit and cost-sharing structures well in advance of a plan year regardless of the market. Accurate rate development is dependent upon detailed projections of covered populations, their predicted health service needs, and their associated costs. Drug manufacturers are the best, most reliable sources of information and can help inform many of these assumptions, including efficacy for certain populations and predicted pricing. Currently, drug manufacturers openly discuss their anticipated appropriate patient populations at scientific conferences and with the investment community as well as with health plans and pharmacy benefit managers, but only to the extent that law allows them to do so in advance of an FDA approval.

Current regulations and their inherent ambiguity can significantly restrict communications by biopharmaceutical manufacturers before a drug has approval to come to market. Manufacturers are unable to make any comments about efficacy or safety claims prior to FDA approval. While there are important reasons to put safeguards around this type of communication, the restrictions have been interpreted in a way that unnecessarily constrains communication between drug manufacturers and payers who must estimate the populations that would benefit from new drugs and determine appropriate reimbursement. Communicating this necessary information, including clinical studies for particular populations, is thus restricted due to current rules, making it extremely difficult to predict plan costs in advance of a new drug coming to market.

The downstream effects of these policies on plan pricing are tangible for enrollees. For example, under Medicare Part D, plans receive reinsurance payments for enrollees with very high drug costs, which significantly fall above the catastrophic threshold. According to the Medicare Payment Advisory Commission (MedPAC), reinsurance is the fastest growing component of the Part D program in large part because plans have consistently underestimated enrollees' expected costs above the catastrophic threshold, resulting in higher reinsurance payments from Medicare to plans over time.[xx]

We urge you to clarify the disclosure rules to better allow drug manufacturers and health plans to discuss scientific studies related to a drug prior to approval, including relevant drug features, such as dosing and

potential pricing. This will allow better budgeting by plans, governments, and employers who use insurers to administer and price health benefits.

Remove Barriers to Value-Based Payments

Current anti-kickback restrictions, certain anti-discrimination rules, Robinson-Patman contracting limitations, and "best" price requirements in Medicaid interfere with adopting robust value-based payment designs and artificially keep drug costs higher than they otherwise would be in the absence of government policy.

- Anti-kickback rules are intended to prevent fraudulent and abusive practices by prohibiting arrangements where organizations or individuals could receive inappropriate payments and benefits to receive one product or service over another. While the intention of these rules is valuable, it has the unintended consequence of hampering the adoption of value-based payment arrangements. For example, anti-kickback rules could prevent plans from creating incentives structured around prescribing medications with high clinical efficacy or rewarding patients for adherence to such therapies. There should be clear exceptions created to these rules allowing for more flexible value-based arrangements and risk sharing based on medical outcomes achieved. This could include a shared savings model in which providers and patients could be incentivized through sharing in overall health savings derived from prescribing and adhering to appropriate high-value prescription drugs that have been shown to improve outcomes and reduce overall health service spending.

- In general, Robinson-Patman requires that a seller treat all competing customers in a proportionately equal manner. The seller must inform all of its competing customers if any services or allowances are available. The seller must allow all types of competing customers to receive the services and allowances involved in a particular plan or provide some other reasonable means of participation for those who cannot use the basic plan. As it applies to the drug manufacturing industry, this means that health plans or PBMs that basically offer the same types of services have to be provided with similar price offerings (within a range). However, in cases where risk-based contracting may be offered, there may be extenuating circumstances where one plan may have a more robust information system to capture patient data, a different delivery network of providers, or some other key factor that would lend itself to the creation of a different contract that may leverage those advantages. Robinson-Patman in its' current form tends to preclude the ability to be flexible in crafting a tailored offer in that manner. Instead, there should be a new framework provided for contract negotiations covered by Robinson-Patman that is sufficiently flexible to permit drug manufacturers and purchasers to pursue risk-based arrangements without requiring manufacturers to provide the same terms to all purchasers in the class. This would provide a safe harbor and allow manufacturers to accept risk for medical outcomes when their products are used under negotiated terms.

- Plans should also be given flexibility to pursue value-based insurance design. For instance, plans should be allowed to change the cost sharing of medications for patients with different diagnoses in a way that will incentivize patients to adhere to treatments with the most potential to improve outcomes for a particular condition. Cost sharing could be reduced for a drug that is highly

efficacious in, say, treating certain types of cancer, while cost sharing could be higher for patients on the same drug but with a type of cancer for which the treatment is less efficacious.

- Drug manufacturers are required to offer Medicaid programs the "best" price for a drug, regardless of what arrangements may have been made in other markets that are structured very differently from Medicaid. This inherently disincentivizes drug manufacturers from entering into more innovative, lower cost arrangements within other markets because the lowest or "best" price must be shared with all state Medicaid programs. These incentives must be aligned properly in order to truly spur innovative value-based design.

Support Medication Adherence to Promote Patient Savings

Policies that improve medication adherence can help patients improve outcomes while lowering systemic costs by avoiding unnecessary, expensive hospitalizations and emergency room visits. Poor medication adherence results in 33 percent to 69 percent of medication-related hospital admissions in our health care system, at a cost of roughly $100 billion per year.[xxi] For example, reforming the Medicare Part D Medication Therapy Management (MTM) program to more accurately target services to beneficiaries in need would help to ensure patients are properly adhering to their medication regimens. A more effective MTM program that coordinates services between Medicare Parts A, B, and D would serve as a step in the right direction toward eliminating the stove piped nature and misaligned incentives inherent within the Medicare program that inhibit medication adherence.

5) Empower Consumers to Make Better Prescription Drug Choices
(Question #4)

Patients should have access to relevant, meaningful, and actionable information so they can make informed decisions about their prescription drugs. We believe doing so will not only empower consumers, but will also improve quality and health outcomes while lowering costs for prescription drugs. Realizing this potential will require the broader availability and use of data to generate meaningful and accurate comparative tools and information on prescription drug, pharmacy, and plan choices. This should be done in a way that supports market competition and does not disclose competitively sensitive information.

Unfortunately, several issues continue to frustrate optimal federal data policy that would contribute to better data, better tools, and better markets for consumers making decisions about their prescription drugs. Among these known problems, we highlight the following:

- Certain current government policies result in missed sharing opportunities, data silos, or the release of data that lack critical context to make information usable to consumers.

- Health care data are often not available in an accessible and relevant format for consumers. Too often, consumers — particularly older Americans — become frustrated or turned-off by confusing jargon and apples-to-oranges comparisons.

- The Medicare Plan Finders for Parts C and D that present Medicare plan options to consumers do not always have user-friendly, accurate, and actionable tools and information.

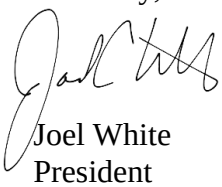
Generally, CMS efforts to date on public data sharing for prescription drugs have lacked an overall vision for why data are released outside of the abstract goal "to improve transparency." The released data may not be particularly helpful or useful (e.g., CMS Medicare prescription drug charge data) for consumers and/or may provide an incomplete picture of actual Medicare spending on prescription medicines by focusing on a small subset of medicines (e.g., the CMS Medicare Drug Spending Dashboard). All too often, drug spending data is presented in a gross data format with little or no context, including the absence of the scope and appropriateness of alternative therapies available, efficacy of treatment, or potential downstream medical savings. This lack of contextual reference in CMS' data releases can be misleading for beneficiaries, market analysts, and the general public. We believe this framework has also unnecessarily contributed to a confrontational atmosphere between payers, patients, providers, and manufacturers, which has often inhibited productive partnerships and conversations to address health care affordability. To better advance shared societal goals (lower costs, better quality, etc.), data and metrics should always be gathered, studied, and released in context to reduce or eliminate confusion, lack of understanding, and/or the potential for misleading information.

Consumers can also benefit tremendously from improved prescription drug and plan coverage comparison tools. For example, private sector comparison tools can provide cost information on the prices of select prescription drugs in various pharmacies to help consumers comparison shop for the best prices. We believe these private sector tools may offer important prescription drug pricing information to the uninsured, as well as for insured consumers that increasingly find themselves in plans with high or full cost sharing for prescription drugs (e.g., high-deductible health plans). Congress should require HHS to ensure data it releases is accurate. We suggest requiring HHS to adopt a strategic plan for its transparency efforts, including for prescription drugs, with achievable and meaningful metrics to gauge success.

Conclusion

CAHC appreciates your careful consideration of our comments. We stand ready to serve as a resource to you and your staff on the issues related to drug prices, costs, and value.

Sincerely,



Joel White
President
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