

**Via Electronic Submission**

March 4, 2016

The Honorable Ron Wyden  
U.S. Senator  
221 Dirksen Senate Office Building  
Washington D.C. 20510

The Honorable Charles Grassley  
U.S. Senator  
135 Hart Senate Office Building  
Washington, D.C. 20510

**Re: Response to January 21 Letter Regarding Senate Print 114-20, “The Price of Sovaldi and Its Impact on the U.S. Health Care System” (Dec. 1, 2015)**

Dear Senators Wyden and Grassley:

The Medicines Company (MDCO) appreciates the opportunity to comment on the important policy issues regarding breakthrough therapies, patient access, marketplace transparency, and “the concept of ‘value’” of innovative therapies addressed in the December 2015 report entitled, “The Price of Sovaldi and Its Impact on the U.S. Health Care System” (the Report),<sup>1</sup> and your letter dated January 21, 2016 (the Letter). In response to your request for public input, we address the critical concept of “value” through the prism of MDCO’s experience as a company that has long been committed to delivering value and integrating value-based approaches in our pricing and contracting strategies. We did that long before the concept of “value-based” purchasing was popularized, and we remain committed to doing so. We have steadfastly pursued and advocated for value-based approaches because we understand that such approaches are not just desirable, but are in fact essential to ensuring meaningful, affordable and sustainable patient access to life-saving and life-improving products, including breakthrough therapies that can provide new and never-before-available treatment options for patients with serious or life-threatening conditions.

We are ardent in our commitment to value-based pricing and contracting, and we are eager to continue as an active partner in our nation’s efforts to evolve toward a system that ensures access and affordability for patients through policies that appropriately incentivize innovation and reward value. In the response that follows, we provide some relevant background about MDCO and our commitment to value-based approaches. We then discuss a number of barriers that have, unfortunately, impeded our efforts to pursue and implement value-based approaches to the fullest extent possible. Notwithstanding these challenges, we are confident that there are feasible pathways forward. To that end, we also offer suggested ways to address the challenges that we identify. Per your Letter’s request, we do so in a manner that “keeps in mind the balance of investing in innovative therapies of the future, with the broader concern of how the American people and health system will be able to afford them.”<sup>2</sup> We look forward to working with you and other stakeholders on these solutions.

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<sup>1</sup> Senate Print 114-20, “The Price of Sovaldi and Its Impact on the U.S. Health Care System” (Dec. 1, 2015), available at <http://1.usa.gov/1QmTpel>.

<sup>2</sup> This letter and its contents are for policy development consideration only; they are not for promotional purposes and are not intended for prescribers or patients. No prescription decision should be made on the basis of these materials, in whole or in part.

## Introduction

MDCO is a global pharmaceutical company focused on advancing the treatment of patients through the delivery of innovative, cost-effective medicines that improve the economic efficiency of hospitals and healthcare systems. We provide solutions for acute/intensive care hospitals worldwide, improving health and economic outcomes related to cardiovascular, life-threatening infection, and surgical events.

Although we are encouraged by a number of the government's statements regarding value-based payments and contracting approaches, there currently exists a fundamental disconnect between the stated goals and prevailing policies. In order to make meaningful and significant progress in the push to pay for value, this disconnect must be addressed. Fortunately, such progress is achievable, and we have a number of workable proposals for policies that can move the healthcare system farther along on this high-priority trajectory.

In particular, we urge Congress to call for better alignment of value-based principles with prevailing policies through implementation of the following improvements:

1. Value-based models will not work unless all parties in the pathway have an aligned interest in the model and an opportunity to participate equally in the implementation, and current bundling methods do not incentivize this. Manufacturers need a clear legal path to participate in risk-sharing and other outcomes- and value-based pricing and contracting arrangements.
2. Market access meaningfully affects patient access. Policies that punish innovation through increased rebate liability or inadequate reimbursement have a significant negative impact on the development and availability of new and improved treatment options. The reality is that price reporting requirements and reimbursement policies can (and often do) influence clinical decisions by providers and development considerations by manufacturers. Thoughtful reforms relating to manufacturer price reporting requirements and healthcare reimbursement policies are necessary and can go a long way in advancing efforts to ensure that (i) patients have access to innovative treatments; (ii) payers are providing appropriate payment for the value delivered by such treatments; and (iii) stakeholders are incentivized to support new products and improvements to existing products.
3. Policymakers should take a close look at the unintended consequences of certain government programs, such as the 340B program, to make sure that the programs are working for patients and for the healthcare system as a whole.

## Overview of Some of Our Products and Development Projects

MDCO's innovator medicines and pipeline products are designed to satisfy unmet medical needs and to address economic challenges and realities, with particular focus on the critical care hospital setting. We brought a number of new medicines to market in 2014 and 2015, and we have additional innovations in the pipeline that illustrate our continued investment in, and commitment to, high-quality care and positive patient outcomes.

For instance, our anti-infectives address infections caused by bacteria that the Centers for Disease Control and Prevention have designated as urgent antimicrobial resistance threats. **Orbactiv**<sup>®</sup> (oritavancin), for example, is an innovative antibiotic that, with a single dose, treats ABSSSI caused by susceptible gram-positive bacteria, including methicillin-resistant *Staphylococcus aureus* (MRSA). In addition, our pipeline product **CARBAVANCE**<sup>®</sup> (meropenem/vaborbactam) is an investigational intravenous antibiotic under development for

treatment of serious bacterial infections due to gram-negative bacteria, particularly KPC-producing CRE (*i.e.*, *Klebsiella pneumoniae* carbapenemase-producing carbapenem-resistant Enterobacteriaceae). Carbavance works by “restoring” the effectiveness of an antibiotic that otherwise is rendered ineffective by the development of resistance.

Orbactiv and Carbavance are FDA-designated as Qualified Infectious Disease Products (QIDPs), intended to treat a serious or life-threatening infection. Orbactiv, particularly given its single infusion regimen, represents a significant advance compared to other antibiotic therapies that involve multiple doses over several days, often requiring hospitalization or repeated visits to an outpatient infusion center. Orbactiv enables providers to reduce the total cost of care by reducing hospital admissions, decreasing the number of outpatient visits, and lowering overall resource utilization. Orbactiv also improves compliance (thereby reducing the risks of antibiotic resistance resulting from incomplete treatments) and lowers the risk of additional hospital-acquired infections or complications, thus improving patient safety and reducing readmissions—all objectives that align with the government’s goals to improve quality while containing costs.

We are eager to pursue value-based contracting for Orbactiv and other products in our portfolio that represent significant advances and deliver value to patients and the healthcare system. Additional examples of MDCO’s innovative products and development projects include (but are not limited to) the following:

- **Kengreal**<sup>®</sup> (cangrelor) is a cardiovascular product approved by FDA in 2015. Kengreal is an intravenous, short-acting inhibitor of adenosine diphosphate (ADP)-induced platelet aggregation that reduces the risk of peri-procedural myocardial infarction, repeat coronary revascularization, and stent thrombosis in adult patients undergoing percutaneous coronary intervention (PCI). Kengreal is a potent, fast-acting, antiplatelet agent with rapidly reversible effects that can address unmet clinical needs.<sup>3</sup>
- **ALN-PCSsc** is a pipeline PCSK9 product that, unlike currently marketed PCSK9 products, is being developed as an RNA interference (RNAi) treatment. Early data indicate that ALN-PCSsc may significantly reduce LDL-C by blocking PCSK9 synthesis with its innovative RNAi mechanism of action.

### **Suggested Improvements to Address Regulatory Barriers to Value-Based Approaches**

In response to your Letter’s first question regarding “the effects of a breakthrough, single source innovator drug on the marketplace,” we note that innovator products have the potential to dramatically improve quality and patient health outcomes. Where they do so, they promise to bend the cost curve and result in long-term cost savings through advances over existing treatments (or an existing unmet medical need) for complicated infections and chronic

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<sup>3</sup> Similarly, our product **Angiomax**<sup>®</sup> (Angiomax) is a direct thrombin inhibitor used for anticoagulation in patients who are undergoing PCI. As compared to the other anticoagulant option used by hospitals and interventional cardiologists in PCI procedures, heparin (which was never approved specifically for PCI by the FDA), Angiomax—which has been on the market for more than 15 years—has been shown to produce improved outcomes (*e.g.*, reduced bleeding and reduced mortality), with attendant cost savings across the spectrum of PCI patients. See, *e.g.*, Bimmer Claessen et al., *Balance of Ischemia and Bleeding in Selecting an Antithrombotic Regimen*, *Intervent. Cardiol. Clin.* 2: 515-525 (2013); Steven Marso et al., *Comparative Effectiveness of Radial Access and Bivalirudin on PCI-Related Bleeding Events in the NCDR<sup>®</sup> CathPCI Registry<sup>®</sup>*, ACC/i2 Scientific Sessions 2010, abstract 2505-458 (2010), available at <http://www.transradialuniversity.com/images/marso.pdf>; Steven Marso et al., *Association Between Use of Bleeding Avoidance Strategies and Risk of Periprocedural Bleeding Among Patients Undergoing Percutaneous Coronary Intervention*, *JAMA*, 303:2156-2164 (2010); Adnan Chhatriwalla et al., *Association Between Bleeding Events and In-hospital Mortality After Percutaneous Coronary Intervention*, *JAMA*, 309:1022-1029 (2013).

conditions. The impact of a breakthrough drug ultimately depends on the nature of the drug, the relevant disease state, the patient population, and a host of other factors.

Importantly, though, the many benefits of breakthrough products cannot be realized if innovation is stifled at either the development or market access stage. Appropriate coverage and reimbursement for innovative products, reflective of the value and pathway savings potential that these new medicines offer, are critical to ensuring market access. This access, in turn, encourages future development. As noted, and in response to your third question, which asks about the role that “the concept of ‘value’ play[s] in this debate,” MDCO strongly supports the “pay-for-performance” model advanced by the government. We believe that value-based approaches in which reimbursement is tied to clinical outcomes or other performance metrics is an appropriate way to balance the cost of breakthrough products with their attendant quality and cost savings benefits. But, before manufacturers can meaningfully engage in value-based approaches, the existing regulatory barriers to value-based contracting must be removed.

First, as a threshold matter, we note that a widely accepted definition for “value” does not currently exist. The value-based purchasing movement is premised on the assumption that such arrangements will impel otherwise isolated providers, manufacturers, payers, and other stakeholders, to coordinate and restructure the delivery of healthcare to erase the earlier inefficiencies that resulted from disjointed decision-making; but, this is not possible without first clearly defining what “value” means and how it is measured. MDCO believes that “value” should be conceptualized in terms of a drug’s *clinical merits* (e.g., efficacy, length/quality of life, patient satisfaction, etc.) *and overall pathway savings* (over a reasonably sustained period of time) based on improved patient health experiences and outcomes.

Under today’s model, decisions relating to hospitals’ purchasing of prescription drugs generally—regrettably—are made solely by pharmacists almost exclusively on the basis of *immediate acquisition cost*, and not on the widely-embraced factors that would reward *value*. This current model ignores savings and improvements in patient care that can be realized in the overall clinical pathway during the course of the admission or thereafter. Hospitals’ assessments of “value” should span across the entire care pathway and cannot rest on a myopic view of acquisition cost alone.

To illustrate the point in an area where MDCO operates, some hospitals have begun to focus on reducing not just the immediate costs of PCI procedures (*i.e.*, solely focused on costs incurred in the cardiac catheterization laboratory), but also on how some additional expenditures associated with the procedure itself can reduce complications, improve outcomes, and reduce overall costs. But other hospitals fail to consider this “bigger value picture,” because they neither have the resources nor incentives to focus on and assess the total cost of care for the entire patient encounter as well as any follow-up costs post-discharge. Value-based purchasing seeks to address this concern by (i) focusing on patient outcomes and the potential for overall cost savings across the broader clinical care pathway, and (ii) allowing manufacturers to collaborate with providers, payers, and other stakeholders to create appropriate incentives for pathways and decision-making processes that move beyond the inefficiencies of today’s fee-for-service model and, ultimately, create mechanisms that motivate all relevant parties to participate.

Second, MDCO has faced a number of barriers in our efforts to pursue value-based contracting. Many of these barriers result from regulatory policies that are within the control of the Department of Health and Human Services (HHS), including, as indicated above, the following: (1) Office of Inspector General (OIG) rules and guidance on the Anti-Kickback Statute (AKS); (2) Centers for Medicare and Medicaid Services (CMS) price reporting regulations and reimbursement policies; and (3) problematic incentives under the 340B program.

The unintended consequence of these incentive structures and regulatory barriers is to obstruct a number of value-based options and approaches, and to undermine the related goals of improving pricing transparency and ensuring patient access. Below, we briefly elaborate on these issues and the resulting disconnect between calls for value-based pricing and contracting, on the one hand, and existing incentive structures and policies in our healthcare system, on the other. In discussing these examples, we also offer suggested improvements that address questions two, four, and five in the Report and Letter.

## 1. **OIG: AKS Risk and the Need for Improved Safe Harbor Protections/Waivers**

To effectuate the “transition to value-based payments for health care” envisioned by the OIG and other government agencies,<sup>4</sup> these efforts must encompass crucial components of healthcare services, including drugs and devices (and their manufacturers). Unfortunately, the OIG’s guidance to date and recent enforcement actions have created uncertainty as to whether value-based arrangements involving manufacturers are clearly protected under existing AKS safe harbors and related guidance. While some arrangements may fit comfortably into the framework of the safe harbors for discounts or personal services, for example, other, more complex arrangements may combine discounts, warranties, and services (as those concepts are defined by the relevant safe harbors).

Further, due to the nature of the clinical information and outcomes being measured in such arrangements, the time and other resources needed to gather and analyze the requisite data may be extensive and may be required to extend over a significant period. It is concerning, therefore, that certain government statements and recent enforcement actions have created confusion and uncertainty about the extent to which discount arrangements that also involve service components can be protected under the relevant safe harbors.<sup>5</sup> Value-based contracts inherently require data collection and other similar service components to measure whether the relevant product satisfies its anticipated value proposition (*i.e.*, clinical outcomes and cost savings) for purposes of administering the applicable agreement. In addition, the OIG’s “same methodology” guidance regarding arrangements that bundle drug and non-drug products raise concerns about whether such bundles can satisfy the AKS discount safe harbor.

As we have explained in public comments filed both this year and last year in response to OIG’s Solicitation of New Safe Harbors,<sup>6</sup> MDCO strongly believes that OIG should create a regulatory safe harbor specific to value-based and/or risk-based contracting arrangements that would protect (and appropriately incentivize) transparent arrangements premised on value- and outcomes-based purchasing. OIG also should consider employing waivers similar to those used for Accountable Care Organizations (ACOs) and CMS Innovation Center models. Without such protections in place, OIG’s policies effectively exclude one of the largest segments of the healthcare system, manufacturers, from value-based arrangements. This exclusion contradicts the shift towards value-based reimbursement models and, ultimately, will impose significant obstacles to the achievement of the government’s stated goals, including improved patient access. Patients will not benefit from the full potential of value-based purchasing unless

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<sup>4</sup> See, *e.g.*, OIG, Management Challenge 2: Transitioning to Value-Based Payments for Health Care, *available at* <https://oig.hhs.gov/reports-and-publications/top-challenges/2013/challenge02.asp>.

<sup>5</sup> See, *e.g.*, U.S. ex rel. Kester v. Novartis, No. 1:11-cv-08196-CM, 2nd Am. Compl. (S.D.N.Y. Jan. 30, 2014); U.S. ex rel. Lisitza v. Johnson & Johnson, Nos. 07-10288, 05-11518, Transcript of Motion to Dismiss (D. Mass Oct. 7, 2010); U.S. ex rel. Gale v. Omnicare Inc., No. 1:10-cv-00127 (N.D. Ohio) (2014); U.S. ex rel. Silver v. Omnicare Inc., No. 1:11-cv-01326 (D.N.J.) (2011) (2014).

<sup>6</sup> OIG, *Solicitation of New Safe Harbors and Special Fraud Alerts*, 80 Fed. Reg. 79,803 (Dec. 23, 2015); OIG, *Solicitation of New Safe Harbors and Special Fraud Alerts*, 79 Fed. Reg. 78,376 (Dec. 30, 2014).

manufacturers are allowed to participate and are, in appropriate circumstances, afforded legal protection in doing so.<sup>7</sup>

## **2. CMS: Need for Reforms Relating to Price Reporting Implications of Value-Based Arrangements and Reimbursement for Innovative Therapies**

### **A. Price Reporting Implications of Value-Based Arrangements**

Despite CMS' statement that it "view[s] value-based purchasing as an important step to revamping how care and services are paid for, moving increasingly toward rewarding better value, outcomes, and innovations instead of merely increased volume,"<sup>8</sup> the Agency has done little outside the context of demonstration projects that could meaningfully enable manufacturers to engage in value-based arrangements—particularly with respect to price reporting. In particular, the impact of value-based, outcomes-based, and risk-sharing arrangements on Best Price (BP) and Average Sales Price (ASP) creates strong disincentives for manufacturers to pursue such arrangements.

Under current regulations, value-based arrangements have the potential to set very low BPs and/or ASPs. The impact on BP can dramatically increase manufacturers' Medicaid rebate liability and the discounts owed under the 340B program. In addition, the impact on ASP can lead to inappropriately low future reimbursement for Part B drugs, which, in turn, can have an adverse impact not only on healthcare providers but also on patient access.<sup>9</sup> Accordingly, if CMS truly seeks to reward value and incentivize innovation, we strongly recommend that the Agency implement BP and ASP exclusions or other policy modifications for drugs purchased pursuant to a value-based contracting arrangement.

### **B. Reimbursement for Innovative Therapies**

Rewarding "value" in the healthcare system necessarily must include policies that provide appropriate reimbursement for innovative therapies. Without appropriate reimbursement, providers will not prescribe therapies, patients will not have access to therapies, and manufacturers will not be incentivized to develop therapies. Unfortunately, MDCO's experiences with our anti-infectives illustrate the disappointing reality that we are actually being *discouraged* to develop a real solution to bug-resistant antibiotics. Medicare payment policies not only fail to incentivize innovation in this important area but, in fact, directly penalize it. Two examples will illustrate the point. First, the "comprehensive ambulatory payment classifications" (C-APCs) under Medicare's hospital outpatient prospective payment system create large bundles of services paid at a rate which, in many cases, negates a hospital's incentive to use an innovative therapy that, while more expensive to acquire initially, can lead to improved outcomes for patients and significant savings for the hospital and the Medicare program over the full course of the clinical care pathway.

As another example, recent rules addressing new technology add-on payments (NTAP) under Medicare's inpatient prospective payment system discourage innovations such as Carbavance by signaling that a product cannot be considered "new" unless *all* of its active ingredients are new molecular entities. This overly restrictive view of "newness" fails to

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<sup>7</sup> See, e.g., John K. Iglehart, *Doing More With Less: A Conversation With Kerry Weems*, HEALTH AFFAIRS, Vol. 28, no.4 (2009):w688-w696; Einer Elhauge, THE FRAGMENTATION OF U.S. HEALTH CARE: CAUSES AND SOLUTIONS 219 (2010) ("[T]he simplest thing would be for Congress or the Office of Inspector General to recognize an explicit exception or establish a safe harbor [to the AKS] for value purchasing.").

<sup>8</sup> See CMS, *Medicare Program; Medicare Shared Savings Program: Accountable Care Organizations*, 76 Fed. Reg. 67802, 67804 (Nov. 2, 2011).

<sup>9</sup> See, e.g., HHS Office of the Assistant Secretary for Planning & Evaluation, Final Report, *Analysis of Supply, Distribution, Demand, and Access Issues Associated with Immune Globulin Intravenous (IGIV)* (Feb. 2007).

appreciate—and thereby directly disincentivizes—innovations such as Carbavance that can *restore the effectiveness* of an existing drug by combining it with a novel, first-in-class agent that *inhibits* the bacterial resistance to the existing drug. Given the growing public health problem of antibiotic resistance, this is the very type of innovation that Medicare should recognize and incentivize. Unfortunately, that has not been our experience to date.

### 3. HRSA: 340B Program’s Unintended Consequences

Congress established the 340B program to help uninsured and underinsured patients gain access to lower-cost outpatient drugs.<sup>10</sup> But, unfortunately, government reports have observed that, through manipulations of patient care pathways and practices that fail to provide discounts to uninsured patients even as the hospitals benefit from low 340B acquisition costs,<sup>11</sup> 340B hospitals are, in many cases, increasing costs for patients, Medicare, and the healthcare system at large in a manner that belies the program’s intent.<sup>12</sup>

Based on our experience, the unintended consequences of the 340B program’s existing incentive structure are to create patient access and clinical pathway concerns, and to disincentivize manufacturers from investing in innovation. Disturbingly, we are aware of a number of actual and potential misuses of the 340B program. One well-known example involves a covered entity that, in the past, publicly touted its practice of discharging recent transplant patients from inpatient status and referring them to a “Townhouse” down the road from the hospital. By doing so, the patients would receive their necessary immune-enhancing therapy on an “outpatient” basis at the Townhouse rather than as inpatients in the hospitals, allowing the covered entity to realize a significant spread between the 340B price and the reimbursed amount. This type of clinical care pathway manipulation for purposes of securing 340B discounts raises serious concerns about patient safety and program integrity. Quite troublingly, this manipulation directly hurts patients. For example, the increased use of observation stays and inpatient/outpatient manipulation is negatively affecting certain Medicare beneficiaries by eliminating coverage for skilled nursing facility (SNF) admissions and increasing beneficiary cost-sharing obligations.

The 340B program also incentivizes 340B providers to purchase *higher cost* drugs, because the 340B entity can realize a greater profit margin when it acquires such drugs at the low 340B acquisition cost and then receives the full reimbursement amount from the payer—including Medicare. Most disturbingly, patients often owe higher co-pays on the higher-priced drugs, meaning that the patient is paying more cost-sharing on the higher-priced drug even if the 340B hospital is paying less to acquire it. These are very perverse incentives that impair access and increase costs for patients, as well as Medicare. Recent government reports

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<sup>10</sup> See H.R. Rep. 102-384 (II), at 13 (emphasizing the 340B program’s focus on improving access to outpatient drug therapies for uninsured and underinsured patients through a focus on discounts to entities “that provide *direct clinical care to large numbers of uninsured Americans*” (emphases added)).

<sup>11</sup> See, e.g., GAO, *Medicare Part B Drugs: Action Needed to Reduce Financial Incentives to Prescribe 340B Drugs at Participating Hospitals*, GAO-15-442 (June 2015), at 14 (finding that notable numbers of 340B hospitals provide low levels of uncompensated and charity care, including as compared to non-340B hospitals); HHS OIG, *Contract Pharmacy Arrangements in the 340B Program*, OEI-05-13-00431 (Feb. 2014); GAO, *Drug Pricing: Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement*, GAO-11-836 (Sept. 2011); Explanatory Statement to H.R. 83 at 11-12 (enacted as Pub. L. No. 113-235 on Dec. 16, 2014), *available at* <http://docs.house.gov/billsthisweek/20141208/113-HR83sa-ES-G.pdf> (stating “concerns that HRSA has been unable to demonstrate that the 340B program benefits the most vulnerable patients”).

<sup>12</sup> See, e.g., GAO, *Medicare Part B Drugs: Action Needed to Reduce Financial Incentives to Prescribe 340B Drugs at Participating Hospitals*, GAO-15-442 (June 2015), at 20 (finding that, “in both 2008 and 2012, per beneficiary Medicare Part B drug spending . . . was substantially higher at 340B [disproportionate share (DSH)] hospitals than at non-340B hospitals”—suggesting that, in general, 340B hospitals prescribed patients more expensive drugs and/or higher volumes of drugs than non-340B hospitals).

confirm these troubling effects on the Medicare program that result from existing 340B incentives, and the GAO has expressly concluded that “Action [Is] Needed to Reduce Financial Incentives to Prescribe 340B Drugs at Participating Hospitals.”<sup>13</sup>

Similarly, HRSA’s guidance relating to “penny pricing” creates even larger spreads that can motivate 340B hospitals to engage in hoarding practices.<sup>14</sup> This, in turn, reduces overall patient access due to product shortages, creates waste in the system, and discourages future investment in innovation. We believe that reducing the profit potential associated with 340B purchasing practices would minimize the risk of clinical care manipulation and hoarding behavior, thereby helping to ensure more appropriate and affordable patient access and helping to reduce costs for Medicare and other payers.

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We reiterate our steadfast commitment to delivering value and our confidence that progress can be achieved in this critically important area. MDCO urges Congress to call for better alignment between the important goals raised in your Report and Letter and the policies of HHS and its agencies. We appreciate your consideration of our comments and suggestions, and we look forward to working with you and HHS in the future to improve the quality of care and outcomes for patients and the opportunities for the healthcare system to pay for value.

Sincerely,



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<sup>13</sup> HHS OIG, *Part B Payments for 340B-Purchased Drugs*, OEI-12-14-00030, at 9 (Nov. 2015) (finding that Medicare Part B payment amounts exceeded 340B ceiling prices by 58% in 2013, and that, for some products, “the difference between the Part B payment amount and the 340B ceiling price was so large that . . . the beneficiary’s coinsurance alone (i.e., 20 percent) was greater than the amount a covered entity spent to acquire the drug”); *see also id.* (noting that 340B entities spent \$737 per treatment in the first quarter of 2013 to acquire a particular cancer drug, but beneficiaries owed \$831 per treatment (i.e., 13% more than the drug cost) through coinsurance paid to the covered entity—and adding that, meanwhile, “in addition to receiving this coinsurance, the 340B entities also received \$3,325 per treatment in reimbursement from Medicare”); *see also* GAO, *Medicare Part B Drugs: Action Needed to Reduce Financial Incentives to Prescribe 340B Drugs at Participating Hospitals*, GAO-15-442 (June 2015).

<sup>14</sup> *See, e.g.,* GAO, *Drug Pricing: Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement*, GAO-11-836 (Sept. 2011).