



January 26, 2016

**BY ELECTRONIC MAIL**

Bipartisan Chronic Care Working Group  
Committee on Finance  
United States Senate  
219 Dirksen Senate Office Building  
Washington, D.C. 20510

**Re: POLICY OPTIONS DOCUMENT**

Dear Members of the Bipartisan Chronic Care Working Group:

Takeda Pharmaceuticals USA, Inc. (Takeda) appreciates the opportunity to provide comments on the December 2015 Policy Options Document released by the Senate Finance Committee's Bipartisan Chronic Care Working Group. Takeda is a research-based global pharmaceutical company with a strong commitment to developing and marketing innovative medicines that offer patients new treatment options, focusing on therapeutic areas with significant unmet needs. Takeda's pipeline products include medicines for some of the most serious and challenging health problems facing Americans. Our marketed products include medicines for the treatment of many chronic diseases including obesity, diabetes, and depression.

Takeda greatly appreciates all the time and effort the Bipartisan Working Group has put into understanding the problems faced by Americans battling chronic diseases and developing options to improve their care. We agree with the group's assessment that initiatives to address the complex issues associated with improving care for chronic conditions should be approached thoughtfully and have a strong evidentiary foundation. Moreover, it is also essential to recognize when the existing evidence supports immediate action.

There is overwhelming evidence to support immediate action allowing Medicare beneficiaries access to FDA-approved prescription medications that help fight obesity. As discussed in this letter, the evidence unequivocally demonstrates a dramatic increase in obesity—including associated healthcare costs—over the last two decades, and that even modest reductions in weight can lead to improved patient outcomes and garner savings for the Medicare program.<sup>1</sup> Instead of attacking the disease head-on with a robust campaign, Medicare is fighting obesity without all available tools at its disposal. No new evidence should be required to mobilize Congress to enact reforms to improve beneficiary health and help rein in Medicare costs.

The use and impact of obesity medications have been evaluated by pharmaceutical manufacturers of weight loss medications<sup>2,3,4,5</sup>. These large-scale clinical studies of obesity medications have been reviewed by the FDA and approved based on their efficacy and safety profiles. Rather than pursue additional studies to "determine the use and impact of obesity drugs in the Medicare and Medicaid system," we urge the Senate Finance Committee to include the provisions of S.1509, *The Treat and Reduce Obesity Act of 2015*, in its legislative options package. This bill and its House companion (H.R. 2404) have the support of more than 130 Members of Congress and reflect bipartisan agreement on the need to allow Medicare coverage of weight loss treatments. These provisions remove Medicare's outdated restriction on Part D coverage of weight loss medication and expand access to intensive behavioral therapy (IBT) -- thus providing Medicare beneficiaries with access to the full range of effective treatments available to fight obesity (weight loss surgery is already covered). Appropriate use of pharmacotherapy in the Medicare population would be guided by the prescribing information of FDA-approved weight management medications. They have a "futility rule" stating if patients do not achieve a 4-

5% weight loss from baseline by 12-16 weeks, the drug should be stopped. This would prevent inappropriate use and unnecessary spending. This critical reform would be consistent with the published management guidelines developed by medical experts in the field of obesity and related fields, including those of the American Association of Clinical Endocrinologists, the Endocrine Society, the American Heart Association, and the National Institutes of Health (NIH).<sup>6,7,8,9,10</sup> These guidelines recognize that pharmacotherapy may be appropriate and required as an adjunct to lifestyle modifications in the management of obesity. These reforms would also bring Medicare into compliance with the American Medical Association (AMA) recommendation for “patient access to the full continuum of care of evidence-based obesity treatment modalities (such as behavioral, pharmaceutical, psychosocial, nutritional, and surgical interventions).”<sup>11</sup>

The Policy Options Document states that the Working Group is “considering requiring a study to determine the use and impact of obesity drugs in the Medicare and non-Medicare populations,” which could “detail the utilization of such drugs and any subsequent impact on medical services that are directly related to obesity, including by subpopulations determined by the extent of obesity; examine medical interventions for individuals not taking obesity drugs; and examine the experience of MA-PDs that cover obesity drugs as a supplemental benefit.”<sup>12</sup>

We appreciate the Working Group’s recognition obesity is a serious problem that is directly related to or exacerbates chronic diseases. However, we respectfully disagree that any further study is needed to produce significant new information beyond the well-documented impacts of obesity and the safety and efficacy of available treatment options. Delaying reform while a study is carried out would have adverse health consequences for many Medicare patients who are struggling with obesity and could result in escalation of obesity-related costs for the Medicare system. The other classes of drugs originally excluded from coverage—smoking cessation, benzodiazepines, and weight gain—were not subjected to a study before coverage. We ask that the most prevalent disease in the U.S. be treated with equal consideration.

It is critically important that we begin fighting the obesity crisis with all the tools available as quickly as possible because adverse health consequences and costs of failing to act are mounting daily. In these circumstances, any study that slows coverage reform would be imprudent. We recommend the coverage of pharmacotherapy as a treatment option for appropriate Medicare patients suffering from obesity.

**I. Existing Evidence Clearly Demonstrates the Need for Making the Full Range of Obesity Treatments Available to Medicare Beneficiaries, and the Value of this Strategy to Medicare and its Beneficiaries**

As described in greater detail in our initial comments to the Working Group,<sup>13</sup> the impact of obesity on patient health and healthcare spending is well documented. Obesity is a chronic disease that is also associated with a broad range of other chronic diseases -- including type 2 diabetes, hypertension, dyslipidemia, metabolic syndrome, osteoarthritis, obstructive sleep apnea, and non-alcoholic fatty liver disease.<sup>14</sup> Numerous randomized, controlled studies demonstrate the clinical benefits of modest weight loss on reducing the incidence of co-morbid conditions (e.g., diabetes, hypertension, dyslipidemia, nonalcoholic steatohepatitis, urinary incontinence, and osteoarthritis); on improving cardiovascular and metabolic parameters; and on measures of emotional and physical functioning.<sup>15,16,17,18,19,20,21,22,23,24,25,26,27,28</sup> For example, results from two major studies, the Diabetes Prevention Program (DPP) and LOOK AHEAD, demonstrated that modest weight loss resulted in major reductions in blood pressure and triglycerides and a significant increase in high-density lipoprotein (HDL) cholesterol.<sup>29,30</sup>

While these problems affect every segment of our population, obesity and its comorbidities disproportionately affect Medicare beneficiaries. Obesity is currently responsible for approximately \$50 billion in annual Medicare spending -- including significant spending on prescription drugs to treat co-morbid conditions.<sup>31</sup> By treating obesity effectively in the Medicare population, we can significantly reduce chronic disease and avoid spending on care needed to treat those conditions.<sup>32</sup> A recent analysis in the Health Economics Review estimated that Medicare would achieve gross savings of \$7,446–\$10,126 per person over ten years from obese beneficiaries' losing 10% of their body weight.<sup>33</sup> Importantly, if overweight and obese Medicare beneficiaries lost just 4.2% of their body weight, the Medicare program would save \$3.8 billion to \$4.7 billion over ten years.<sup>34</sup>

Currently, four prescription medications have been approved by the Food and Drug Administration (FDA) to help people achieve weight loss and more could be on the horizon. As an example, Contrave® (naltrexone HCl and bupropion HCl) Extended Release Tablets is a prescription weight loss medication indicated for adults (including the elderly) with a body mass index (BMI) of 30 kg/m<sup>2</sup> or greater (obesity) or 27 kg/m<sup>2</sup> or greater (overweight) who have at least one weight-related condition such as hypertension, type 2 diabetes mellitus, or dyslipidemia. The efficacy of Contrave was evaluated in four 56-week, randomized, controlled trials (Contrave Obesity Research, or COR-I, COR-II, COR-Behavior Modification [BMOD], and COR-Diabetes) in conjunction with lifestyle modification in 4,536 obese and overweight patients.<sup>35,36,37,38</sup> All patients received lifestyle modification that consisted of a reduced-calorie diet and regular physical activity. In all four trials, patients randomized to Contrave achieved significantly more weight loss and maintenance compared to patients randomized to placebo at 56 weeks. In the COR-BMOD trial, which combined Contrave with a behavioral modification program, the Contrave group achieved a -9.3% weight reduction compared to -5.1% in the placebo group at week 56 (P < 0.001). Additionally, the percentages of patients with ≥ 5% body weight loss from baseline was significantly greater with Contrave compared with placebo (mITT-LOCF: 66.4% vs 42.5%, respectively) (P < 0.001).<sup>39,40</sup>

As a group, the newer prescription drug treatments have been summarized recently as follows:

Responding to the medical need for better treatment options in obesity, the FDA has approved 4 new obesity medications since 2010: phentermine/topiramate, lorcaserin, bupropion/naltrexone, and liraglutide. Each of these drugs met FDA criteria for efficacy, namely providing sustainable weight loss of 5% or more—either on average or in more than 50% of patients treated. Consistent with guidelines for obesity care, this level of efficacy was shown to provide significant improvements in diabetes, cardiovascular disease, and quality of life.<sup>41</sup>

Currently, the Medicare statute creates a large gap in the options available to beneficiaries who need to lose weight: Medicare covers counseling (IBT) and bariatric surgery for certain Medicare beneficiaries, but not prescription drugs. Thus, while there is a continuum of treatments available to fight obesity, Medicare currently covers only the ends of the continuum: the intermediate option is non-covered. However, patients with obesity are rarely using the treatments that are currently covered by Medicare, which means they remain obese and are deprived of access to pharmacotherapies that have been shown effective. For example, fewer than 1% of Medicare beneficiaries have used Medicare's free weight-loss counseling.<sup>42</sup> And only 1% of patients who qualified for bariatric surgery between 2011 and 2013 chose to undergo the surgery,<sup>43</sup> which has good effectiveness data but, like many surgeries, can be a difficult option for patients to choose. Moreover, bariatric surgery is only recommended for a subset of obese patients, and reoperation may be necessary with an associated increase in operative and post-operative morbidity and mortality.<sup>44</sup> Weight loss drugs, in addition to diet and exercise, offer a viable alternative for many Medicare beneficiaries.

By excluding weight loss medications from Medicare Part D coverage,<sup>45</sup> the Medicare statute restricts Medicare beneficiaries' access to the full continuum of treatments to fight obesity and impedes their efforts to achieve weight loss goals that could improve their health and help reduce costs to the Medicare program. Yet another result of this care continuum gap is that the ability to learn more about the issues the Working Group identified as the potential focus of further study is very limited. Without coverage under Part D, Medicare beneficiaries rarely use weight loss medications. Without real world coverage and utilization, new data is sparse. And further analysis of existing data would unlikely yield new insights on how broader utilization of weight loss drugs would affect particular subpopulations or the healthcare services they use.

## **II. Provisions of *The Treat and Reduce Obesity Act of 2015* Should Be Included as Part of the Legislative Package to Improve Care of Chronic Diseases to Promote the Full Continuum of Care and Capture Medicare Savings**

Studying the impact and utilization of obesity drugs will not close the gap in the continuum of care for obesity treatment. In contrast, *The Treat and Reduce Obesity Act* would improve the treatment of obesity in Medicare beneficiaries by expanding access to treatment options that are less invasive than bariatric surgery. The bill would allow Part D coverage of FDA-approved prescription medication for treatment of obesity or for weight loss management for an overweight individual with one or more related comorbidities. It also would cover IBT for obesity furnished by additional types of providers than are currently recognized as Medicare providers (provided the services are furnished upon referral from, and in coordination with, a physician or primary care practitioner in a setting specified by the Department of Health and Human Services).

These provisions would meet the three key goals the Working Group identified for policies under consideration:

1. The proposed policy increases care coordination among individual providers across care settings who are treating individuals living with chronic diseases;
2. The proposed policy streamlines Medicare's current payment systems to incentivize the appropriate level of care for beneficiaries living with chronic diseases; and
3. The proposed policy facilitates the delivery of high quality care, improves care transitions, produces stronger patient outcomes, increases program efficiency, and contributes to an overall effort that will help reduce the growth in Medicare spending.

*The Treat and Reduce Obesity Act* would increase care coordination across settings by expanding access to IBT when provided in coordination with primary care providers. By providing coverage of weight loss drugs, the bill would improve access to treatment options that are less invasive than bariatric surgery and allow beneficiaries and their physicians to select the most appropriate level of care. By improving access to these treatment options, *The Treat and Reduce Obesity Act* will facilitate the delivery of high quality care and improve patient outcomes by giving patients and their physicians additional tools to promote weight loss and reduce comorbid conditions; that is, the bill will fill in the gap in the continuum of care and thus allow Medicare patients and their physicians to select the most appropriate evidence-based treatment for the individual patient. Overall, Medicare spending would be expected to decline as the need for treatment of comorbid conditions is reduced.

The magnitude of the obesity problem we face today clearly warrants this sensible reform. The obesity rates we have experienced in the last two decades are considered an epidemic,<sup>46</sup> with obesity-related healthcare

costs accounting for an estimated 8.5% of total annual Medicare spending.<sup>47</sup> The costs of putting off coverage reform are high. As a recent article warned:

Although the overall prevalence of obesity may be reaching equilibrium at an unacceptably high rate, the rate of severe obesity is continuing to grow and is driving tremendous growth in the burden of chronic diseases. Obesity is a key driver, for example, of chronic liver disease, and is becoming a key factor in the growing need for liver transplantation. Obesity is increasingly recognized for contributing to growth in the prevalence of many forms of cancer. All this is in addition to the long-recognized relationship with cardiovascular disease and diabetes.

So health plans are indeed paying a high price for treating the consequences of untreated obesity. Without evidence-based treatment, obesity persists, progresses, and causes chronic diseases that affect virtually every organ system.<sup>48</sup>

Therefore, we urge the Working Group to include the provisions of *The Treat and Reduce Obesity Act* in its legislative package. If it were not possible to include those provisions (particularly Section 4 providing Part D coverage for obesity medications) in their current form, then modest substantive modifications might alleviate concerns about such coverage and permit the inclusion of a meaningful obesity drug benefit in the chronic care legislative proposal. Alternate legislative language (see footnote) could be considered to allow those Medicare beneficiaries with a BMI of 35 or 30 to 34.9 and one or more comorbidities related to obesity to access FDA-approved obesity medications if they can demonstrate they have tried prior weight loss.<sup>49</sup> This approach would be greatly preferable to a study of obesity medications as it would advance the Bipartisan Working Group's goal of improving care for patients with chronic diseases. A substantive provision that provides some measure of obesity drug coverage for Medicare patients is patently the right policy choice; delaying coverage while awaiting the results of a study is not.

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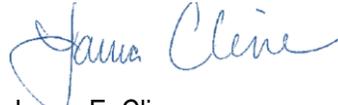
<sup>49</sup> **DRAFT LEGISLATIVE LANGUAGE: Sec. \_\_ MEDICARE PART D COVERAGE OF OBESITY MEDICATION.**

(a) In General. - Section 1860D-2(e)(2)(A) of the Social Security Act (42 U.S.C. 1395w-102(e)(2)(A)) is amended by inserting after "restricted under section 1927(d)(2)," the following: "other than subparagraph (A) of such section if the drug is used for the treatment of obesity or for weight loss management for an individual who (1) has a body-mass index of 35, kg/m<sup>2</sup> or greater, or (2) has a body-mass index of 30 to 34.9, kg/m<sup>2</sup> and has one or more comorbidities related to obesity."

(b) Effective Date. - The amendment made by subsection (a) shall apply to plan years beginning on or after the date that is one year after the date of the enactment of this Act.

We urge the Senate Finance Committee and its Bipartisan Working Group to embrace and work to enact this simple and long-needed reform, which already enjoys bipartisan support and would give Medicare patients more tools to combat obesity. Thank you again for giving us the opportunity to comment on the Working Group's Policy Options Document and for recognizing that obesity must be addressed for the future health of Medicare beneficiaries and the program. Please contact Shelley Stewart at 202-649-4010 with any questions.

Sincerely,



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Takeda Pharmaceuticals U.S.A., Inc.

## End Notes

- <sup>1</sup> Matrix Global Advisors LLC, Budgetary Impact of Obesity in the United States (May 2014), [http://static1.1.sqspcdn.com/static/f/460582/24917990/1400697928903/Matrix\\_ObesityCoalition\\_Final.pdf?token=J6gSHxSuvMhmhOtYbBu5D1gPUBA%3D](http://static1.1.sqspcdn.com/static/f/460582/24917990/1400697928903/Matrix_ObesityCoalition_Final.pdf?token=J6gSHxSuvMhmhOtYbBu5D1gPUBA%3D)
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- <sup>12</sup> Policy Options Document at 30.
- <sup>13</sup> Takeda letter to Senate Finance Committee, June 19, 2015.
- <sup>14</sup> VA/DoD Clinical Practice Guidelines for Screening and Management of Overweight and Obesity, at 8-9 (May 2014)(citations omitted), available at <http://www.healthquality.va.gov/guidelines/CD/obesity/VADoDCPGManagementOfOverweightAndObesityFinal.pdf>
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- <sup>46</sup> Matrix Global Advisors LLC, Budgetary Impact of Obesity in the United States (May 2014).
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