June 19, 2015

BY ELECTRONIC MAIL

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

Re: Request for Input Regarding Improving Outcomes for Medicare Patients with Chronic Conditions

Dear Members of the Bipartisan Chronic Care Working Group:

Takeda Pharmaceuticals USA, Inc. (Takeda) appreciates the opportunity to provide comments in response to the Chronic Care Working Group's request for input on policies to improve outcomes for Medicare patients with chronic conditions. 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. Our marketed products include medicines for the treatment of many chronic diseases including diabetes, depression, gout, and obesity. Takeda's pipeline products include medicines for some of the most serious and challenging health problems facing Americans, including Alzheimer's disease.

Our comments focus on a critical issue that has received little attention in the discussion of chronic care management: improving health outcomes for patients with obesity and, in doing so, controlling healthcare spending. Obesity, itself a chronic disease, is associated with many other chronic diseases. In updated Clinical Practice Guidelines for Screening and Management of Overweight and Obesity issued in 2014, the Department of Veterans Affairs and the Department of Defense described the scope and severity of the obesity epidemic we face today in striking terms:

> The evidence clearly links overweight and obesity with an increased risk of chronic health conditions and reduced quality of life, as well as earlier mortality among those with class II and III obesity. Overweight and obesity are associated with increased prevalence and worsening of several obesity-associated conditions, including type 2 diabetes, hypertension, dyslipidemia, metabolic syndrome, osteoarthritis, and obstructive sleep apnea. The CDC estimates that 9 out of 10 people diagnosed with type 2 diabetes are overweight or obese. Furthermore, as a result of the obesity epidemic, the lifetime risk of developing type 2 diabetes for an individual born in 2000 is 33%. The development or worsening of type 2 diabetes, hypertension, and dyslipidemia is particularly hazardous due to the independent effects on risk for coronary artery disease and stroke.
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> In addition to the aforementioned obesity-associated conditions, excess body weight is the most important risk factor for the development of non-alcoholic fatty liver disease (NAFLD) which has recently emerged as a major health problem in the western world. The exact prevalence in the general adult population is unknown, but ranges from 10 to 46%. It is now the most common form of liver disease in the US.

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> One study estimates that approximately 40% of NAFLD will progress to nonalcoholic steatohepatitis. NAFLD has surpassed alcohol as a reason for liver transplants in the US and will likely become the leading condition necessitating liver transplants (ahead of hepatitis C) within 10-20 years.[1]

Importantly, obesity and its comorbidities also disproportionately affect Medicare beneficiaries.[2] By treating obesity effectively in the Medicare population, we can significantly reduce chronic disease and Medicare spending.[3] Today, we can no longer view obesity as a lifestyle choice or a problem that can be solved by diet and exercise alone: the American Medical Association (AMA) has recognized obesity as a chronic disease since 2013.[4] Subsequently the AMA issued formal policy supporting "patient access to the full continuum of care of evidence-based obesity treatment modalities such as behavioral, pharmaceutical, psychosocial, nutritional, and surgical interventions." If we are to reduce the burden of chronic disease for Medicare beneficiaries and cut Medicare spending, Medicare must treat this chronic and debilitating disease in the same way it treats diabetes, heart disease, or any other chronic disease -- which themselves may be caused by obesity.

Obesity is responsible for approximately $50 billion in annual Medicare spending.[5] Yet Medicare is fighting obesity without all available tools at its disposal. Currently, there are several FDA-approved prescription pharmaceuticals to help people combat obesity and more are on the horizon, yet Medicare is prohibited by law from covering these drugs.[6] As a country, we do not withhold insulin from a diabetic patient or antihypertensive medicines from a person suffering from high blood pressure. Now that obesity is formally recognized as a chronic disease by the AMA, it is remarkable that we continue to withhold medical treatments from persons suffering with obesity, especially since multiple organizations such as American Association of Clinical Endocrinologists, The Endocrine Society, and American Heart Association have all publically supported the role of pharmacotherapy in the management of obesity. We can no longer accept that status quo; the time has come to develop policies which streamline Medicare's current payment systems to incentivize the appropriate level of care for patients living with this chronic, and often debilitating, disease.

For the reasons described below, we urge the Senate Finance Committee to move forward with revising the Medicare statute so that these medicines are available to Medicare beneficiaries who need more options to fight obesity. Today it is critically important that we enact legislation to modernize the Medicare statute and make the full range of effective treatments for obesity available to Medicare beneficiaries who are suffering from this disease. S 1509, *The Treat and Reduce Obesity Act of 2015*, introduced by Senators Tom Carper, Chuck

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[1] 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

[2] Matrix Global Advisors LLC, Obesity in the Medicare Population: Opportunities for Cost Savings (Oct. 2014), http://static1.1.sqspcdn.com/static/f/460582/25536305/1412959668483/Matrix_ObesityMedicare_100614.pdf?token=Znx5I2iwT%2BIGi1RYv9srGQiMjCs%3D

[3] ibid.

[4] *See* New York Times, "A.M.A. Recognizes Obesity as a Disease" (June 18, 2013), *available at* http://www.nytimes.com/2013/06/19/business/ama-recognizes-obesity-as-a-disease.html?_r=0

[5] 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

[6] Section 1927(d)(2) of the Social Security Act has a list of drugs that "may be excluded from coverage or otherwise restricted by states under Medicaid. This list includes "agents when used for . . . weight loss. . . ." Under Medicare Part D, section 1860D-2(e)(2) of the Social Security Act excludes the drugs listed in section 1927(d)(2) from Part D coverage, *available at* http://www.ssa.gov/OP_Home/ssact/title18/1860D-02.htm, http://www.ssa.gov/OP_Home/ssact/title19/1927.htm

Grassley, Bill Cassidy, Martin Heinrich, Lisa Murkowski, and Chris Coons and referred to your Committee, would ensure these treatment options are available to Medicare beneficiaries.

I. OVERVIEW OF AMERICA'S OBESITY EPIDEMIC

Takeda applauds the Senate Finance Committee's bipartisan goals that include giving careful consideration to policies that contribute to an overall effort that will reduce the growth of Medicare spending. Obesity has been deemed an epidemic in the United States, and we need to continue to create smart strategies to address this health problem. Specifically:

The startling increase in obesity rates we have seen in the last two decades is considered an epidemic.[7]

- Obesity, which affects 93 million Americans, is a chronic disease for which the benefits of chronic disease management are well known.[8]
- Obesity is the second leading cause of preventable deaths and is linked as a direct cause of cancer, high blood pressure, heart disease, diabetes, and stroke.[9]
- Today approximately 35% of American adults—and 40% of Americans aged 65-74—suffer from obesity.[10]
- Since the mid-1980s, obesity has been linked to a one-third increase in the cost of private insurance premiums, Medicare, and Medicaid spending.[11]

Health care costs associated with obesity are responsible for 8.5% of total annual Medicare spending.[12]

- Using this measure, a recent study concluded that approximately $50 billion of the $585 billion in 2013 Medicare spending was attributable to obesity.[13]
- According to a study published in 2012, the impact of obesity on a person's annual medical costs is $2,741 (in 2005 dollars) on average.[14] The authors of the study note that their results "indicate that insurance companies spend more treating obesity than was previously thought, and thus there may be a better business case for insurance companies to cover effective treatments for obesity (such as prescription drugs for weight loss, bariatric surgery, and nutritional counseling) than was previously appreciated."[15]

Federal health care programs especially feel the brunt of obesity costs. One study found that, "[t]hrough Medicare and Medicaid, federal and state governments finance approximately half of direct medical expenditures

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[7] Matrix Global Advisors LLC, Budgetary Impact of Obesity in the United States (May 2014), see attached.

[8] Obesity Action Coalition, "Understanding Obesity," *available at* http://www.obesityaction.org/understanding-obesity

[9] *See* N.Y. Dept. Public Health, "Obesity Prevention," *available at* https://www.health.ny.gov/prevention/obesity; Centers for Disease Control and Prevention, "The Health Effects of Overweight and Obesity," *available at* http://www.cdc.gov/healthyweight/effects

[10] Matrix Global Advisors LLC, Budgetary Impact of Obesity in the United States (May 2014), see attached

[11] Kenneth Thorpe, The Future Cost of Obesity: National and State Estimates of the Impact of Obesity on Direct Health Care Expenses (2009), *available at* http://www.nccor.org/downloads/CostofObesityReport-FINAL.pdf

[12] Eric A. Finkelstein et al., Annual Medical Spending Attributable to Obesity: Payer- and Service-specific Estimates, 28 Health Affairs 822 (Sept. 2009), *available at* http://content.healthaffairs.org/content/28/5/w822.long

[13] 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

[14] John Cawley and Chad Meyerhoefer, The Medical Care Costs of Obesity: An Instrumental Variables Approach, 31 J. Health Economics 219 (2012), *available at* http://www.nber.org/papers/w16467

[15] ibid.

attributable to overweight and obesity in the U.S."[16] *This is not surprising, given the high prevalence and incidence of chronic diseases associated with obesity among the elderly.*

- The prevalence of diabetes among all U.S. adults is 12.3%, while the prevalence among adults 65 and over is 25.9%.[17]
- Comorbidities, such as diabetes, are typically more expensive to treat among the elderly population.[18] One recent study concluded that a 10% reduction in the obesity rate among the Medicare population would save the Medicare program $281.5 million in costs associated with type 2 diabetes, $138.9 million in costs associated with hypertension, $45.7 million in costs associated with osteoarthritis, $42.2 million in costs associated with colorectal cancer, and $11.5 million in costs associated with breast cancer.[19]

Even modest reductions in weight can lead to improved patient outcomes and large cost savings for insurers.

- Modest (5-10%) weight loss is associated with improvements in cholesterol, blood pressure, and blood sugar.[20]
- If overweight and obese Medicare beneficiaries lost 4.2% of their body weight, the Medicare program would save $3.8 billion to $4.7 billion over ten years.[21]

Not only does weight loss reduce healthcare costs in general, it also reduces prescription drug spending.

- Studies have found that prescription drug spending is cut nearly in half by weight loss, decreasing from $150 per month to $77 per month after weight loss.[22] It makes little sense from either a patient health or an economic perspective for Medicare to deny beneficiaries access to prescription weight loss drugs and instead to cover the drugs to treat chronic conditions that result from obesity.

II. OBESITY TREATMENTS AND THEIR AVAILABILITY TO MEDICARE PATIENTS

We are delighted that the Senate Finance Committee is soliciting ideas on the effective use and cost of prescription drugs. Today Medicare covers counseling (intensive behavioral therapy) and bariatric surgery for certain Medicare beneficiaries, but not prescription weight management—or obesity.[23] Thus, while there is a spectrum of treatments available to fight obesity, Medicare currently covers only the ends of the continuum: the intermediate option is unavailable under current law.

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[16] J. Lee et al., Coverage of Obesity Treatment: A State-by-State Analysis of Medicaid and State Insurance Laws, Pub. Health Rep., 2010, *available at* http://www.publichealthreports.org/issueopen.cfm?articleID=2469

[17] Matrix Global Advisors LLC, Obesity in the Medicare Population: Opportunities for Cost Savings (Oct. 2014), http://static1.1.sqspcdn.com/static/f/460582/25536305/1412959668483/Matrix_ObesityMedicare_100614.pdf?token=Znx5I2iwT%2BIGi1RYv9srGQiMjCs%3D

[18] Ibid.

[19] Ibid.

[20] *See* Rena R. Wing et al. Long-term effects of a lifestyle intervention on weight and cardiovascular risk factors in individuals with type 2 diabetes mellitus: four-year results of the Look AHEAD trial. 170 Arch Intern Med. 1566 (Sept. 2010), *available at* http://www.ncbi.nlm.nih.gov/pubmed/20876408

[21] 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

[22] Ibid.

[23] Social Security Act §§ 1860D-2(e)(2), 1927(D)(2)), *available at* http://www.ssa.gov/OP_Home/ssact/title18/1860D-02.htm, http://www.ssa.gov/OP_Home/ssact/title19/1927.htm

The options provided by Medicare are not enough: patients with obesity are not using the treatments currently covered, which means they remain obese. For example, fewer than 1% of Medicare beneficiaries have used Medicare's free weight-loss counseling.[24] On the other end of the spectrum (both in terms of health risks and cost), only 1% of patients who qualified for bariatric surgery between 2011 and 2013 chose to undergo the surgery,[25] 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 recent studies of long-term outcomes show weight loss is not always sustained,[26] and reoperation may be necessary with an associated increase in operative and post-operative morbidity and mortality.[27]

Clearly, neither counseling alone nor bariatric surgery is right for all Medicare patients, and weight loss drugs, in addition to diet and exercise, offer a viable alternative for many Medicare beneficiaries. The fact that Medicare does not pay for groundbreaking pharmaceuticals approved by the FDA for obesity and/weight management appears to be an unjustifiable anomaly that should not continue to stand. The restricted range of choices available to Medicare patients today stems from a 1992 decision by Congress to permit states, at their discretion, to exclude "agents when used for anorexia, weight loss, or weight gain" from Medicaid coverage,[28] and then from a 2003 Medicare Modernization Act provision that made the list of drugs that are excludable by states from Medicaid coverage entirely excluded from Medicare Part D, with Part D plans not even having discretion to cover drugs in these categories.[29]

III. ENDING FRAGMENTATION AND DISRUPTIONS IN CARE FOR PATIENTS SUFFERING FROM OBESITY WHO ARE ENROLLING IN MEDICARE

In its stakeholder letter, the Senate Finance Committee also appropriately requested strategies for more effective coordination of prescription drugs. For patients with chronic diseases, a critical element of care coordination and management is maintaining benefits when their circumstances change. Today patients in a number of Federal health programs, as well as privately insured patients, have coverage for pharmacotherapy for weight loss. More specifically:

- the Veterans Health Administration covers weight management drugs;[30]
- the Indian Health Service covers weight management drugs;[31] and
- the Federal Employee Health Benefits Program covers weight loss drugs, with the Office of Personnel Management emphasizing in 2014 guidance that FEHB plans may not exclude coverage of newly approved anti-obesity medications on the ground that obesity is a "cosmetic" or "lifestyle"

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[24] Phil Galewitz, "Seniors' Obesity-Counseling Benefit Goes Largely Unused, USA Today (Nov. 15, 2014), *available at* http://www.usatoday.com/story/news/nation/2014/11/15/obesity-counseling-benefits-fails-to-entice-seniors-doctors/18914149/.

[25] Jaime Ponce et al., "New Procedure Estimates for Bariatric Surgery: What the Numbers Reveal," American Society for Metabolic and Bariatric Surgery, *available at* http://connect.asmbs.org/may-2014-bariatric-surgery-growth.html

[26] Karmali S et al. Weight recidivism post-bariatric surgery: a systematic review. Obes Surg. 2013:23(11);19922-33. Hsu LK et al. Nonsurgical factors that influence the outcome of bariatric surgery: a review. Psychosom Med. 1998: 60(3):338 -46, *available at* http://elementalhealthcare.co.uk/files/9914/0672/3412/Karmali_Weight_Recidivism_Post-Bariatric_Surgery_2013.pdf

[27] Brenthauer SA et al. Systematic review on reoperative bariatric surgery surgery: American society for Metabolic and Bariatric Surgery Revision Task Force. Surg Obes Relat Dis 2014; 10 (5): 952-72. Doi:10.1016/j.sourd.2014.02.014, *available at* https://asmbs.org/wp/uploads/2014/05/SystematicReviewReoperativeBarSurg-Feb2014.pdf

[28] Social Security Act § 1927(d)(2)((A), *available at* http://www.ssa.gov/OP_Home/ssact/title19/1927.htm

[29] Social Security Act § 1860D-2(e)(2)(B), *available at* http://www.ssa.gov/OP_Home/ssact/title18/1860D-02.htm

[30] Department of Veterans Affairs, "Under Secretary for Health's Information Letter: the Managing Overweight and/or Obesity for Veterans Everywhere (MOVE!) Program," *available at* http://www.move.va.gov/docs/MoveInfoLetter.pdf

[31] Indian Health Service, IHS National Pharmacy and Therapeutics Committee Antiobesity Medications (Feb. 2014), *available at* http://www.ihs.gov/NPTC/documents/NPTCFormularyBriefWeightLoss.pdf

issue,[32] a change that took effect in 2015 and affects 2.7 million federal employees and their families.[33]

Obesity and its comorbidities disproportionately affect seniors, as discussed earlier. And yet when patients who now have health coverage for weight loss drugs they are taking turn 65 and shift to Medicare coverage, they lose access to drugs they have been relying on to help control their weight.

Maintaining continuity of care is a central tenet of managing serious and complex chronic conditions effectively. As stated in a recent *Health Affairs* blog article, "[c]ontinuity of care is a bedrock principle of the patient-doctor relationship and is believed to be a fundamental attribute of high-quality medical care. Mounting evidence suggests that continuity of care for patients with chronic conditions prevents hospitalizations, reduces health care costs, and may prolong life in some populations."[34]

Yet today we are failing to follow this bedrock principle of chronic care management for people with obesity. If they currently have coverage for weight management prescription drugs and are working to lose weight, once they age into the Medicare program that coverage disappears. These disruptions in care will grow over time as more insurers extend coverage to these medicines. Congress must act now to avoid these setbacks for individuals who are struggling to fight obesity. Otherwise, these setbacks will continue in the Medicare program, as its new enrollees lose access to therapies that were helping them lose weight and avoid comorbid diseases. Ending this archaic Part D exclusion is an essential first step in improving the coordination and continuity of care for Medicare beneficiaries. Medicare Part D coverage of these FDA-approved prescription drugs will result in patients staying on weight loss drugs longer, seeing their physician more frequently, and losing more weight.[35] We must no longer allow the Medicare program to undo progress achieved by obese patients in fighting this chronic disease.

IV. CONCLUSION

Combating obesity must be a priority in any policy to improve care to Medicare beneficiaries with chronic conditions. Medicare should ensure that physicians and patients have available a full range of therapeutic options to address obesity. At present, Medicare Part D enrollees who need weight loss drugs lack coverage; they would have to pay for the drugs out of pocket or seek some other source of payment. Making these products available through Medicare should improve compliance with physicians' prescriptions and help reduce obesity and obesity-related illnesses. Instead of spending billions of dollars on interventions to treat the chronic diseases associated with obesity, Medicare should instead reduce the incidence of these chronic diseases by using the full arsenal of treatment options available to combat obesity.

This change would build on reforms made by a series of recent laws. As our understanding of certain health problems has grown over time, some exclusions from Medicare Part D coverage no longer make sense. Recognizing this problem, Congress has gradually eliminated or narrowed exclusions that now seem

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[32] Office of Personnel Management, FEHB Program Carrier Letter, Supplemental Guidance: Management of Obesity in Adults (March 20, 2014). C, *available at* https://www.opm.gov/healthcare-insurance/healthcare/carriers/2014/2014-04.pdf

[33] The Advisory Board Company, Feds offer guidance on how to cover obesity treatment- OPM sets standards of federal employee health plans, in Daily Briefing, The Advisory Board Company, 2014, *available at* http://www.advisory.com/daily-briefing/2014/04/03/feds-offer-guidance-on-how-to-cover-obesity-treatment

[34] Joseph Ladapo and Dave Chokshi, Continuity of Care for Chronic Conditions: Threats, Opportunities, and Policy, Nov. 18, 2014, *available at* http://healthaffairs.org/blog/2014/11/18//continuity-of-care-for-ch

[35] Risser JA, Vash PD, Nieto L. Does prior authorization of sibutramine improve medication compliance or weight loss? Obes Res. 2005:13(1):86-92, *available at* http://onlinelibrary.wiley.com/doi/10.1038/oby.2005.11/pdf

counterproductive, such as drugs for smoking cessation. This proposal would extend the same treatment to drugs for weight loss to help address obesity and obesity-related chronic diseases such as diabetes. We urge the Senate Finance Committee to embrace and work to enact this simple and long-needed reform, which would give Medicare patients more tools to combat obesity. Please contact Shelley Stewart at 202-649-4010 with any questions.

Sincerely,

David Dieter
Vice President, Government Affairs
Takeda Pharmaceuticals America, Inc.