



October 27, 2011

The Honorable Daniel Inouye
Chairman
Committee on Appropriations
U.S. Senate

The Honorable Thad Cochran
Ranking Member
Committee on Appropriations
U.S. Senate

The Honorable Harold Rogers
Chairman
Committee on Appropriations
U.S. House of Representatives

The Honorable Norm Dicks
Ranking Minority Member
Committee on Appropriations
U.S. House of Representatives

Dear Appropriations Committee Chairs & Ranking Members:

On behalf of the Obesity Care Continuum (OCC), we applaud the Senate Appropriations Committee for including report language regarding obesity treatment in Senate Report 112-73, which accompanies H.R. 2112, the Agriculture, Rural Development, Food and Drug Administration, and Related Agencies FY 2012 appropriations bill. The Senate report language directs the Food and Drug Administration (FDA) to report to Congress by March 30, 2012 on steps the agency plans to take to support new treatments for obesity in any long-term funding measure for FY 2012 appropriations:

Obesity Therapeutics- The Committee is concerned with the absence of novel medicines to treat obesity, the second leading cause of preventable deaths in the United States and a disease linked to cancer, high blood pressure, heart disease,

diabetes, and stroke. With only diet, exercise, and gastric surgery as options, the lack of obesity medications is a significant unmet medical need. The Committee directs FDA to report by March 30, 2012 on the steps it will take to support the development of new treatments for obesity, including the use of its Risk Evaluation and Mitigation Strategy and other post-marketing authorities, to mitigate risk and ensure rigorous post-market scrutiny while increasing access to novel medications.

The Senate Report correctly identifies the overwhelming public health risks posed by obesity and the staggering cost to the federal government. Medical costs to treat diseases from obesity exceed a staggering \$90 billion per year, half of which is paid by Medicare and Medicaid. Moreover, coverage for prescription medications for obesity is prohibited under Medicare and rare under Medicaid and private health insurance.

National costs attributable to obesity and overweight have been estimated at \$270 billion annually, including direct medical costs and indirect costs, such as absenteeism and productivity losses. Furthermore, “according to its 2009 studies of 187 U.S. metro areas, Gallup estimates that the direct costs associated with obesity and related chronic conditions are about \$50 million per 100,000 residents annually”. It is important to note that, modest weight loss carries significant health benefits alleviating or even eliminating costly co-morbidities driving medical expenses. Therefore, obesity treatment options that lie between diet and exercise and bariatric surgery would play a significant role in managing healthcare costs.

For example, newly reported data from the recent 6th Annual Obesity and Wellness Congress states that 10% weight loss in patients age 60-64 may result in \$8 billion in Medicare savings over 10 years and \$35 billion over their lifetime. Achieving these savings to the federal budget will not be possible without new drug treatments and a change in Medicare and Medicaid coverage policies.

Over the last twelve months, the FDA has made decisions regarding the three new drug applications brought before it for the treatment of obesity. In each case, the FDA chose to either reject or delay approval. All three of these drugs had evidence supporting their efficacy, but were also associated with a slightly higher incidence of certain adverse events in a small subset of patients. We feel the risk to these subsets of the patient population can be mitigated with appropriate strict indications and dosing requirements for those seeking access to these promising new drugs.

These three new promising obesity drugs all met the FDA’s February 2007 draft “Guidance for Industry Developing Products for Weight Management.” And while there may be some slight increase in health risk for certain patient populations, we believe that the agency could easily move forward by allowing these drugs to reach the marketplace by restricting patient populations and indications and rigorous control of access. Such an approach, coupled with post marketing safety-trials, would be

congruent with how the agency has approached new medication approval for other diseases and conditions. We also wish to emphasize that untreated obesity poses far greater health risks than any that have been reported with these medications.

Requiring the FDA to report to Congress on its efforts in this area is an important step in creating the necessary regulatory climate to stem the tide of obesity and obesity-related co-morbidities such as cancer, high blood pressure, heart disease, diabetes, and stroke. We commend the Senate Committee on Appropriations for including this critical FDA reporting requirement and we urge you to retain the language in Senate Report 112-73 in any Continuing Resolution or Omnibus appropriations bill that ultimately funds the government through FY 2012.

Sincerely,



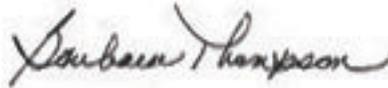
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Barbara Thompson
OAC Chair of Board of Directors
Pittsburgh, Pennsylvania

With a combined membership of over 125,000 healthcare professionals and patient advocates, the Obesity Care Continuum is dedicated to promoting access to, and coverage of, the continuum of care surrounding the treatment of overweight and obesity. The OCC also challenges weight bias and stigma oriented policies – whenever and wherever they occur. The OCC is a coalition of the Obesity Action Coalition (OAC), the Obesity Society (TOS), the American Dietetic Association (ADA), and the American Society for Metabolic and Bariatric Surgery (ASMBS)