May 1, 2008

The Honorable Max Baucus
United States Senate
511 Hart Senate Office Building
Washington, D.C. 20510

The Honorable Charles Grassley
United States Senate
135 Hart Senate Office Building
Washington, D.C. 20510

Dear Chairman Baucus and Ranking Member Grassley,

We know that you are working together with your colleagues in the United States Senate to pass legislation that would halt a scheduled reduction in the Medicare physician fee schedule and make other needed improvements to the Medicare program. We are writing to strongly encourage you to include in any final Medicare package this year a meaningful demonstration program to provide coverage for interventions to help address overweight and obesity among Medicare beneficiaries.

The Strategies to Overcome and Prevent (STOP) Obesity Alliance represents a diverse group of health care providers, payers, patient groups, quality-of-care organizations, labor unions and businesses. The mission of the STOP Obesity Alliance is to move beyond awareness and consumer education efforts to identify and address systemic barriers to individual success in reducing obesity, overweight, and weight-related health risks, including heart disease and diabetes. Last year, the STOP Obesity Alliance issued a series of policy recommendations to assist private sector leaders and public policymakers in achieving this overarching goal. These recommendations are attached and also may be found at http://www.stopobesityalliance.org/insights.htm.

As you know, our public programs have significant gaps when it comes to implementing effective strategies to reduce the burden of heart disease, diabetes and other health risks related to being obese and overweight. These programs are also spending large amounts to care for these conditions – over $46 billion dollars according to a study of national costs attributed to both overweight and obesity. Therefore, consistent with the recommendations that the Alliance released this year, we believe that any demonstration program should examine the effectiveness of interventions aimed at reducing overweight and obesity among adults. Ideally, an effective demonstration program would be available to Medicare beneficiaries and would not be limited only to those eligible for Medicaid.

We applaud you for your commitment to implementing evidence-based strategies to reduce the burden of overweight and obesity and the chronic conditions often associated with being overweight or obese. We hope that the STOP Obesity Alliance can continue to be a resource to the Committee as you consider legislation in this area. Should you have any further questions regarding our policy recommendations or the effective design of a demonstration program under Medicare and Medicaid, please do not hesitate to contact us.

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Sincerely,

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STOP STRATEGIES TO OVERCOME & PREVENT OBESITY ALLIANCE

STOP Obesity Alliance Policy Recommendations

Recommendation One: Re-Vision Success

Explore the use of a *five to ten percent sustained reduction of current weight* as the appropriate measure of success for the purpose of determining whether treatment interventions and innovations are effective.

Currently, success in sustained weight loss is evaluated based upon different definitions of success by patients, providers and researchers. However, a growing body of evidence suggests that losing somewhere between five to ten percent of current weight leads to major improvements in key health areas, including diabetes, lipid blood levels, and even mortality. The National Heart, Lung, and Blood Institute, part of the National Institutes of Health examined a wide-array of randomized controlled studies and recommended a ten percent reduction in weight to achieve lower blood pressure, lower LDL-cholesterol and triglycerides, increased HDL-cholesterol and lower blood glucose levels and decreased incidence of Type-2 diabetes.

For the purposes of mitigating the health and productivity impact of overweight and obesity, a consensus definition of the amount of sustained weight loss necessary to improve health would help us evaluate the efficacy of overweight and obesity interventions and inform reimbursement policies and health benefit design by public and private third party payers and employers accordingly.

Some research has shown that increased physical activity leading to fitness improves the health of people with overweight and obesity independent of weight loss. There is not yet, however, agreement in the medical research about consistent definitions and measures of fitness. Future recommendations about defining success may include fitness or other functional outcomes associated with the improved health and quality of life for people with overweight and obesity.

Most individuals who are overweight or obese and many of their health care providers have unrealistic weight-loss goals; few succeed in achieving those goals. These unrealistic goals may be to achieve a societal norm that is mostly cosmetic. Promoting the health improvements that result from a five to ten percent sustained weight loss could help focus the dialogue on obesity towards healthy outcomes.

The Stop Obesity Alliance Recommends:

- Promoting the use of a sustained loss of five to ten percent of current weight as a key measure to judge the effectiveness of weight reduction interventions.

*** The Strategies to Overcome and Prevent (STOP) Obesity Alliance is sponsored by sanofi-aventis U.S. LLC.*

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Recommendation Two: Encourage Innovation and Multifactorial Interventions to Strengthen the System of Care for Overweight and Obesity

Aggressively explore multifactorial interventions that can achieve a five to ten percent sustained weight loss for those whose condition has not been successfully addressed solely by nutrition and physical activity and for whom bariatric surgery is not an option. Motivate payers, insurers and employers to encourage innovation around these treatments and disease management.

Few research studies and clinical programs have described effective interventions for patients with lower levels of overweight or obesity, before obesity becomes severe and co-morbidities develop. At a BMI of 40, (or a BMI of 35 with co-morbidities), bariatric surgery may become an effective option for treatment for some individuals.

The paucity of effective treatments is compounded by the dominant focus of obesity research on single interventions. Furthermore, these interventions are often carried out in a homogenous group of patients, often without including details on individual characteristics that could guide "real-world" application and help clinicians to tailor treatments for different individuals. Studies often report a range of results from minimal to large, without information indicating for whom treatments were most or least successful.

Consequently, there is an urgent need to develop, test, and evaluate interventions that include multiple components (surgery + behavioral treatment + diet, for instance, or personal trainer + diet + drugs, diet and exercise plan) among diverse populations at lower levels of overweight and obesity, *before* co-morbidities develop. Eventually, this effort may lead to the creation of screening tools that could help match an individual patient's characteristics and needs with appropriate interventions.

While individuals who are overweight or obese seek help and advice in many non-medical settings, primary care providers, and in some cases specialists who are acting in a primary care capacity, see many people with overweight or obesity, whether for weight management, treatment of co-morbidities, or both. As such it is important that these providers are positioned to provide effective screening and treatment to people across the weight spectrum, from lower to more severe levels of overweight and obesity. Various research studies on primary care physician practice patterns have shown, however, that these providers often do not provide such services, due to a number of factors including time, knowledge of treatment modalities, and potential discomfort with broaching the topic with patients.[1]

To achieve these goals, the STOP Obesity Alliance recommends:

- Encouraging innovation around treatments, intervention and disease management with support from employers, insurers, and other payers.

[1] See, for example: Bardia, A.; Holtan, S.; Slezak, J.M.; Thompson, W.G. (2007). Diagnosis of obesity by primary care physicians and impact on obesity management. *Mayo Clin Proc* August 2007;82(8):927-932.

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- Supporting efforts by professional organizations to train health professionals, in order to develop and disseminate best practices for obesity treatment that incorporate tailoring treatments for individuals to achieve maximal results.

- Identifying and disseminating successful or promising practices for interventions.

- Encouraging governmental and non-governmental entities to focus on translating the research on obesity management into recommendations for best practices in the care of obese and overweight individuals.

Recommendation Three: Address and Reduce Stigma as a Barrier to Improving Health Outcomes

Cultivate a positive environment by promoting awareness and open discussion among health professionals, opinion leaders, role models (e.g., parents, teachers, coaches) and the public of the harmful impact of stigmatizing people with overweight and obesity and promote interventions that provide support for sustained weight loss and go beyond recognizing the role of personal responsibility.

There is no evidence that stigmatizing overweight and obese individuals motivates them to lose weight. In fact, stigmatization may postpone and even prevent these individuals from getting treatments that could improve their health. Similarly, providers without effective treatments to offer may avoid discussions about obesity out of fear of offending their patients. Stigma and fear of offending people with overweight and obesity can silence patients and providers and keep them from addressing obesity directly and constructively. Personal responsibility for behavior change is critical to successful sustained weight loss. But, until recently, the discussion of personal responsibility has been the beginning and the end of the obesity debate. To effectively address this epidemic, we must also deal with broader societal barriers to reducing obesity.

Individual perceptions of the causes and prospects for reducing obesity among patients, providers and payers may influence decisions about obesity treatment, particularly in a time of health care cost containment. Cultivating a positive environment, will allow for open and honest discussions about stigma, and increased understanding about the environmental and individual causes of obesity are likely to reduce the stigma of being obese, thus reducing this barrier to successful treatments.

The STOP Obesity Alliance recommends:

- Incorporating educational messages about the environmental and individual causes of obesity.

- Including awareness messages into obesity public initiatives conducted by both government and private entities.

- Supporting efforts to include stigma awareness and training for health professionals.

- Facilitating inclusion of people who are obese or overweight in the development and dissemination of awareness messages and efforts.

- Encouraging the inclusion of measures of access to health care services by ensuring medical technology is accessible and comfortable for people who are overweight or obese (e.g., MRIs, beds, wheelchairs, mammography facilities).

- Engaging in ongoing research on the impact of stigma as it relates to: the pursuit of successful weight management tools; the willingness of the overweight and obese to seek help; the relationship between weight and socio-economic status; and the willingness of public and private decision makers to invest in individual treatment.

- Finding language for health care providers to approach the topic of weight loss in a way that leads to an effective and open discussion with patients.

Recommendation Four: Broaden, Intensify and Coordinate the Research Agenda for Obesity

Encourage an interdisciplinary research environment that addresses the obesity epidemic as a result of a complex interplay of biological, genetic, behavioral, cultural, environmental, social, policy and economic factors.

Throughout the current research landscape, most contributing factors of overweight and obesity are examined separately, with little research or agreement on how aspects of one domain influence another. There is a need for an enhanced collaborative effort among both governmental and non-governmental entities to study all of the important factors contributing to the obesity epidemic and how they interact with each other. The research agenda should examine both the factors and impact of obesity as it relates to health services, socio-economics, the health care system, benefit design, environmental factors/costs, and other broad issues that may affect the epidemic.

Policy makers need reliable information to assess the relative value of addressing the obesity epidemic directly. What are the impacts on productivity, military preparedness, employment patterns and international competitiveness? Addressing how overweight and obesity affects these areas, and encouraging research that addresses a broad spectrum of root causes and contributors to overweight and obesity will become increasingly important as this epidemic progresses.

The STOP Obesity Alliance recommends the formation of a broadened research agenda that includes the following four areas:

- *Clinical Research*

    - Clinical research that measures the impact of incremental weight loss—e.g., five to ten percent—on health improvements across the spectrum of, and tailored to, the severity of overweight and obesity.

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- Clinical research that measures the impact of interventions on non-weight health outcomes (such as exercise to improve fitness and quality of life) for improved health of people who are overweight or obese.

- Explore re-defining what constitutes "evidence" for obesity interventions – overweight and obesity result from a combination of factors interacting with each other; successful interventions are also likely to be multi-component, with no single intervention ensuring widespread success. Yet, the standard for evidence-based medicine, the randomized controlled trial, is ideally suited to assess the effect of a single cause or intervention. It is time to reconsider how to rigorously evaluate interventions that do not fit the single cause-and-effect standard to incorporate both environmental and individual factors important for ameliorating obesity.[2]

- *Actionable Research*

  - Develop and disseminate best practices to translate successful or promising interventions to real-world practice including clinical, school, worksite and community-based settings. For example, practice-oriented translational research approaches can be used to identify and overcome barriers to the dissemination, adoption and sustainability on:
    - Effective implementation of evidence-based practices;
    - Establishment of effective and economical modes of care; and
    - Effective and economical health promotion strategies.[3]

- Develop rigorous methods that answer questions such as, "Do treatments work in the real world of everyday practice?" or "For whom do interventions work best?" For example, use of a "practice-based evidence for clinical practice improvement" can fill gaps in information needed by clinical and health policy decision makers and facilitate better understanding of what occurs when interventions developed in controlled environments with small samples of people are applied in the field with thousands of people with diverse backgrounds and needs.[4]

- *Health Services and Policy Research*

- Applied health services research to address the immediate needs of payers, providers, individuals, employers and other stakeholders who are on the front lines of the obesity epidemic. For example, research is needed to better understand how treatment for

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[2] Jain A. Treating obesity in individuals and populations. *British Medical Journal* 331:7529 (December 2005), 1387-1390.

[3] "Translational Research Overview." University of Connecticut Health Center, The Ethel Donaghue Center for Translating Research Into Practice and Policy. Available at: http://trippcenter.uchc.edu/Translation_Research/research.htm. Accessed November 8, 2007.

[4] Horn, S.D., and Gassaway, J. (2007). Practice-based evidence study design for comparative effectiveness research. *Medical Care*: 45(10) Suppl 2. S50-S57.

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obesity and its comorbidities is affected by access to care issues related to third-party health insurance coverage design in both the public and private sectors.

- Additional cost-benefit analysis on interventions related to overweight and obesity for both public and private sectors
- *Quality Measurement and Improvement Research*
    - Support efforts by NCQA to develop measures on the evaluation and treatment of obesity in primary care settings.
    - Support efforts by NQF to create a nationally-endorsed framework for quality measurement and public reporting for the prevention and treatment of obesity across the continuum of care.

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