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Docket No. FDA-2012-N-0967  
Document Number: 2012-23454  
Prescription Drug User Fee Act Patient-Focused Drug Development; Public Meeting and Request for  
Comments  
October 31, 2012

To The Honorable Leslie Kux  
Assistant Commissioner for Policy, U.S. Food and Drug Administration

Thank you for the opportunity to comment on the Food and Drug Administration's (FDA) plans to provide for a more systematic approach for obtaining patient perspectives on the impact of disease on patients, the spectrum of severity for those who have the disease, the measures of benefit that matter most, and the adequacy of the existing treatment options.

On behalf of the undersigned members of the Strategies to Overcome and Prevent (STOP) Obesity Alliance, we strongly recommend selecting obesity as one of the 20 disease areas the agency prioritizes for this new and critical undertaking.

For your background, the STOP Obesity Alliance is a diverse coalition of consumer, provider, government, labor, business, health insurers, and quality-of-care organizations that have been working together over the past five years to challenge and change how America approaches the problem of obesity, overweight and weight-related health risks. The Alliance's work, based at The George Washington University School of Public Health and Health Services, Department of Health Policy, has centered on developing a series of reports, policy recommendations and tools for consumers and policy makers that are evidence based and approved by consensus.

While the Alliance does not specifically endorse any individual treatments, we are aligned on the need to increase understanding of obesity, focus on weight as a matter of health not appearance, explore multifactorial interventions, and expand the research agenda.

The following STOP Obesity Alliance members support the recommendation to include obesity among the 20 disease areas in the FDA's patient-focused initiative and have signed on to the attached comments:

- American College of Preventive Medicine
- American Sleep Apnea Association
- American Society for Metabolic and Bariatric Surgery
- American Society of Bariatric Physicians
- Harvard Medical School
- National Hispanic Medical Association
- National Hispanic Health Foundation
- National Indian Health Board
- Nebraska Medical Association

- American Society for Nutrition
- Black Women's Health Imperative
- National Association of Chronic Disease Directors
- National Black Nurses Association
- Canyon Ranch Institute
- Central Virginia Health District
- Commissioned Officers Association of the U.S. Public Health Service, Inc.
- DiabetesSisters
- Georgia Department of Public Health
- George Washington University Medical Faculty Associates, Lipid Research Clinic and Cardiac Prevention Clinic
- Obesity Action Coalition
- OWL-The Voice of Midlife and Older Women
- Reality Coalition
- Red Hot Mamas North America
- Society for Women's Health Research
- Trust for America's Health
- William Dietz, MD, Former Director, Division of Nutrition, Physical Activity, and Obesity, Centers for Disease Control and Prevention

Sincerely,



Scott Kahan  
Director, Strategies to Overcome and Prevent Obesity Alliance  
The George Washington University

### **Criteria for Disease Area Selection**

The STOP Obesity Alliance supports FDA's proposed criteria for disease area selection. These criteria will accurately identify the diseases through which FDA might benefit most by exploring a patient-focused drug development approach. The coalition also encourages FDA to prioritize inclusion of disease areas that meet all or multiple criteria, particularly those that represent the extremes of the defined criteria.

### **Rationale for Including Obesity**

The Alliance's research team at The George Washington University (GW) recently completed The GW Obesity Drug Outcome Measures Project<sup>1</sup> that helps define how a patient-centered approach to obesity differs from the current paradigm.

Based on this research and the Alliance's core recommendations, obesity is an ideal candidate for inclusion in these patient-focused meetings. It meets all of the proposed criteria for disease selection and represents an extreme case for many of the proposed criteria, as outlined below:

- ***Disease areas that are chronic, symptomatic, or affect functioning and activities of daily living***  
Obesity is a complex, chronic relapsing health condition with many overlapping causes and consequences. Obesity is associated with numerous medical, physical, and psychosocial conditions that significantly impact an individual's feeling, functioning, and survival.<sup>ii,iii,iv</sup>
- ***Disease areas that reflect a range of severity***  
The population of individuals with obesity is not homogenous; rather, obesity varies in severity, onset and expression of symptoms, and comorbid conditions. Some individuals affected by obesity have associated serious health effects or limitations, while others may have no immediate health consequences or impairments to their daily feeling or functioning.<sup>v</sup> Individuals with obesity fall on a spectrum scale.
- ***Disease areas for which aspects of the disease are not formally captured in clinical trials***  
Because obesity can manifest in a wide variety of ways, treatment may result in many health benefits, reductions in symptoms, and improvements in quality of life. Many of the ways in which obesity impacts individuals are not captured in current drug trials, creating confusion for patients, providers, and regulators over what constitutes an efficacious drug. Any treatment modality to treat obesity should address the complex multifactorial nature of the condition.
- ***Disease areas that have severe impact on identifiable subpopulations (such as children or the elderly)***  
While obesity is highly prevalent among all populations, it is also prevalent and can be severe across the pediatric and adolescent population.<sup>vi, vii</sup> Children and adolescents with obesity are significantly more likely to develop severe obesity as adults.<sup>viii</sup> Clinicians are increasingly relying on surgical interventions in extremely obese adolescents. Clinicians need a variety of safe and effective options to treat their pediatric patients with obesity.
- ***Disease areas that represent a broad range in terms of size of the affected population***  
Over one in three individuals are obese, with an additional one in three overweight and at risk for obesity.<sup>ix</sup> Prevalence trends indicate that obesity will continue to rise in most populations, and may rise significantly among the child and adolescent population.
- ***Disease areas for which there are currently no therapies or very few therapies, or the available therapies do not directly affect how a patient feels, functions, or survives***  
There is a clear need for safe and effective treatment modalities for obesity. Traditional approaches to lifestyle intervention – exercise, diet, and behavioral modification – and other policy measures attempting an environmental impact alone are unlikely to curtail the burden of obesity and obesity-related comorbidities such type 2 diabetes and cardiovascular disease.

Currently available treatment options, both pharmaceutical and non-pharmaceutical, may produce modest weight loss for some individuals. However, most weight loss interventions experience high dropout rates and a significant proportion of those seeking clinical treatment do not respond adequately to traditional diet, exercise, and/or behavioral modification. Long-term weight maintenance is perhaps even more challenging. Emerging evidence suggests that strong physiological pathways may defend against weight loss and promote weight regain, further emphasizing the need for expanded treatment options.<sup>x</sup>

We strongly urge FDA to include obesity for all the aforementioned reasons. Further, we encourage FDA to release more detailed information on how outcomes of these meetings might ultimately be incorporated into the regulatory system.

**Sources:**

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<sup>i</sup> Ferguson C, David S, Divine L, et al. Obesity drug outcome measures: A consensus report of considerations regarding pharmacologic intervention. Available at:

<http://sphhs.gwu.edu/releases/obesitydrugmeasures.pdf>

<sup>ii</sup> Ferguson et al.

<sup>iii</sup> Thompson D, Edelsberg J, Colditz GA, Bird AP, Oster G. Lifetime health and economic consequences of obesity. *Archives of Internal Medicine*. 1999;159(18):2177-2183.

<sup>iv</sup> Bray GA. Medical consequences of obesity. *J Clin Endocrinol Metab*. 2004;89(6):2583-2589.

<sup>v</sup> Ortega FB, Lee D, Katzmarzyk PT, et al. The intriguing metabolically healthy but obese phenotype: Cardiovascular prognosis and role of fitness. *European Heart Journal*. 2012. doi: 10.1093/eurheartj/ehs174.

<sup>vi</sup> Ogden CL, Carroll MD, Kit BK, Flegal KM. Prevalence of obesity in the United States, 2009–2010. NCHS data brief, no 82. Hyattsville, MD: National Center for Health Statistics. 2012.

<sup>vii</sup> Field AE, Cook NR, Gillman MW. Weight status in childhood as a predictor of becoming overweight or hypertensive in early adulthood. *Obes Res*. 2005;13(1):163-169. Accessed 28 September 2012.

<sup>viii</sup> Sorof J, Daniels S. Obesity hypertension in children: A problem of epidemic proportions. *Hypertension*. 2002;40(4):441-447. Accessed 28 September 2012.

<sup>ix</sup> Ogden 2012.

<sup>x</sup> Sumithran P, Prendergast LA, Delbridge E, et al. Long-term persistence of hormonal adaptations to weight loss. *N Engl J Med*. 2011;365(17):1597-1604.